

Radiation Doses in Medical Imaging

**Historical development, current radiation knowledge and future
optimizing tools**

**Thesis by
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List of publications

1. Borgen L, Østensen H, Gudmundsen TE, Stranden E, Olerud HM. Shift in imaging modalities of the urinary tract over a 25-year period and its impact on ionizing radiation doses given to patients. *Scandinavian Journal of Urology and Nephrology* 2007; 41: 110-114
2. Borgen L, Østensen H, Stranden E, Olerud HM, Gudmundsen TE. Shift in imaging modalities of the spine through 25 years and its impact on patient ionizing radiation doses. *European Journal of Radiology* 2006; 60: 115-119
3. Borgen L, Stranden E, Espeland A. Clinicians' justification of imaging: do radiation issues play a role? *Insights into Imaging* 2010; 1:193–200
4. Borgen L, Lærum F, Hachette IW, Fredriksson C, Sandborg M, Kalra M, Smedby Ö. Application of adaptive nonlinear 2D and 3D post-processing filters for reduced dose abdominal CT. *ACTA Rad*, accepted for publication.

Abbreviations

2D filter	Two-dimensional filter
3D filter	Three-dimensional filter
CED	Collective effective dose
CT	Computed tomography
CTDI	Computed tomography dose index
DAP	Dose area product
DLP	Dose length product
DRL	Dose reference level
EC	European Commission
ERR	Estimated excess relative risk
Gy	Gray
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiation Protection
KAP	Kerma area product
LAR	Lifetime attributable risk
LNT theory	Linear non-threshold theory
LRD	Local representative dose
MRI	Magnetic resonance imaging
MSCT	Multi-slice computed tomography
NRPA	Norwegian Radiation Protection Authority
Sv	Sievert
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
US	Ultrasound

1. Preface

I was introduced to medical research and radiation protection issues by the former head of my department, Associate Professor Tor Erik Gudmundsen. Within the Department of Radiology at Drammen Hospital (called Buskerud Central Hospital until 2010) there has been a tradition of focusing on radiation protection issues, and the department quite early introduced non-x-ray-based modalities of ultrasound (US) and magnetic resonance imaging (MRI). Professor Gudmundsen had earlier been doing works on modality shifts following the introduction of new technology, and he encouraged me to look into these issues from a radiation protection viewpoint.

Working as a consultant radiologist, one could overwhelmed by the ever-increasing volume of imaging being requested. When analyzing large numbers of images with insignificant findings, the question of justification automatically comes up. Performing increasingly more multiphase, multi-organ multi-slice computed tomography (MSCT) examinations, one might wonder to what degree referring clinicians are aware of the radiation burden inflicted on their patients, and to what degree radiation protection issues are part of the justification process. The idea of exploring these questions through a questionnaire was developed in collaboration with Professor Erling Stranden at the Buskerud University College and Associate Professor Tor Erik Gudmundsen.

Looking into ways of reducing doses from CT examinations, an optimization project for abdominal CT was established. My principal supervisor, Frode Lærum, put me in contact with Professor Örjan Smedby at the Center for Medical Image Science and Visualization (CMIV) in Linköping. In collaboration with CMIV and Contextvision, a Swedish company developing imaging processing programs, we set up a project for a limited clinical evaluation of a novel three-dimensional (3D) post-processing filter for low dose MSCT images.

2. Acknowledgements

The present studies were carried out at the Department of Radiology at Drammen Hospital in collaboration with colleagues at the Department of Health Sciences at Buskerud University College, the Center for Medical Image Science and Visualization in Linköping, the Divisions of Thoracic and Cardiac Imaging at Massachusetts General Hospital, the Department of Surgical Sciences at the University of Bergen and at the University of Oslo. The work was funded by Drammen Hospital and the Norwegian Society of Radiology.

I am grateful to the former head of the Department of Radiology at Drammen Hospital, Associate Professor Tor Erik Gudmundsen, for introducing me to medical science. His enthusiasm for research, and his pragmatism and large work capacity helped me get started on the studies leading to this thesis. Harald Østensen, former Coordinator at the Team for Diagnostic Imaging and Laboratory Technology, WHO, Geneva, Switzerland, was helpful when I was writing the first papers, and I am grateful for his contribution. I would also like to thank the current head of my department, Åse Tangerud, for being supportive and giving me time to do research, in spite the lack of radiologists in our department and the increasing volume of images to be read.

From 2008, Professor Frode Lærum at the Department of Radiology at Akershus University Hospital has been my principal supervisor. I am thankful for the way he agreed to my request to be my supervisor when establishing my PhD project. Besides practical research guidance and support in the writing process, his open-minded friendliness, curiosity and pleasant personality have inspired me throughout the work on the thesis.

I am also grateful to Professor Erling Stranden at the Department of Health Sciences, Buskerud University College for his enthusiastic guidance. His great knowledge of radiation issues has been invaluable, and our regular at times day to day contact has helped me to make progress with the thesis. Hilde Olerud, head of Section for Quality Assurance in Radiology, Norwegian Radiation Protection Authority, made great contributions to the first two papers of the thesis. Associate Professor Ansgar Espeland at the Department of Surgical Sciences, Section of Radiology, University of Bergen generously shared his time and interest in the third paper. I am indebted to him for his close collaboration on the manuscript and his thorough contributions. I would also like to thank Professor Örjan Smedby at CMIV, for receiving me so warmly and helping me establish the optimizing project of the fourth paper. Thanks also to Martin Hedlund, Isabelle Wegmann Hachette and Carina Fredriksson at Contextvision, for their work with filter tuning and image post-processing.

Many thanks to Are Hugo Pripp (PhD) at the Biostatistics Unit, Research Services Department, Oslo University Hospital, Oslo for his assistance with statistical issues, and to the six radiologists who carried out the image quality evaluation in the fourth paper: Hege Iveland, Åse Tangerud, Kristin Mellingen, Claudius Pieper, Kjartan Aasekjær and Harald Bergan. Thanks also go to Elin Rotstigen for sharing her radiation protection knowledge, to Jan Håvard Kjelle and Margrete Renaa for technical support, and to Ingeborg B. Mortensen and the other radiographers at our CT laboratory. I am also grateful to Marit M. Knudsen and Linda M. Warhuus at the medical library at Drammen Hospital, for their assistance with literature searches and retrieving relevant articles.

Finally, my utmost gratitude goes to my dear wife and best friend Tove, for her support, humor and love, to our three precious children Lavrans, Amalie and Benedikte, and to my parents for their caring and support.

3. Introduction and Background

3.1 Historical and technological development of medical imaging

After the discovery of x-rays by the German physicist Wilhelm Conrad Roentgen in 1895, the new x-ray technology was rapidly applied in clinical medicine. In Norway, the first x-ray machine was purchased by Lovisenberg hospital in Oslo as early as 1897, and the x-ray department at Drammen Hospital was established in 1905 (1).

The radiological techniques remained basically unchanged until about 1970, diagnostics being based on plain films and fluoroscopy, but after decades with little technological progress, new promising modalities emerged. Computed tomography (CT) was developed in the early 70s by Sir Godfrey Newbold Hounsfield and Allan McLeod Cormack (2), an invention for which they received the Nobel Prize for Medicine in 1979. During the 1980s, the CT technology was mainly consolidated, but the advent of spiral and multi-detector CT technology during the 1990s created a renaissance for this modality (3). The ultrasound (US) technique had been known for decades (4), but was refined and adopted for clinical use during the late 70s and early 80s. The first human MRI studies were published in 1977, and Paul Lauterbur and Sir Peter Mansfield received the Nobel Prize for their discoveries concerning magnetic resonance imaging in 1993. Drammen Hospital installed its first CT in 1979. A few years later, in 1983, US was put to use, and in 1992 the radiological department had its first MRI installed.

Together with this technological development, well tolerated intravenous contrast agents have been introduced and applied for MRI, MSCT, and US (5-7). The contrast media enables better visual differentiation of normal tissue and of tumors, inflammation and other pathological conditions.

The development of new modalities, well tolerated contrast agents and powerful computers has led to an amazing development within the field of medical imaging. Different modalities are now able to image organ anatomy as well as physiological and pathological processes in two, three or four dimensions, including time. Short acquisition times, especially for MSCT, enable imaging in different contrast phases and visualization of tissue differences based on vascularization and circulatory differences. The development of dual source MSCT allows for high temporal resolution as well as visualization of chemical tissue differences (8-10). Real time imaging of contrast-enhanced ultrasound is another example of a relatively new technique.

The fusion of Positron Emission Tomography (PET) with CT and MRI into PET-CT(11) and MRI-PET (12) combines the high sensitivity to disease activity of functional imaging with the high quality structural imaging of MSCT and MRI.

3.2 Increased use of medical imaging

The technological development of new modalities and imaging protocols together with an increased scanner distribution, have caused a marked increase in the volume of medical imaging. In Norway, the examination frequency increased from 1983 to 2002, while remaining about unchanged from 2002-2008 (13) (Figure 1).

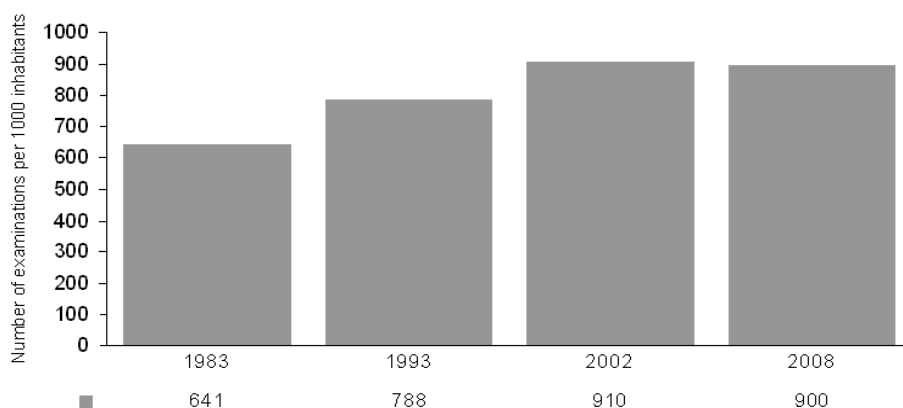


Figure 1. Number of radiological examinations per 1000 inhabitants from 1983 to 2008 in Norway (13).

In the United States, the number of radiologic procedures increased about 10-fold from 1980-2006 (14). The use of MSCT (Figure 2) and MRI has grown exponentially) (15;16), and the costs of imaging increased more than the increase of total healthcare costs of several cancer patient groups in the United States (17) during the period 1999-2006. Besides the development of new technology and increased scanner density (18), there are many other factors contributing to the increased imaging volume, such as self-referral (19), economic incentives, defensive medicine and medico-legal matters (20), 7increased patient expectations and patient autonomy (21).

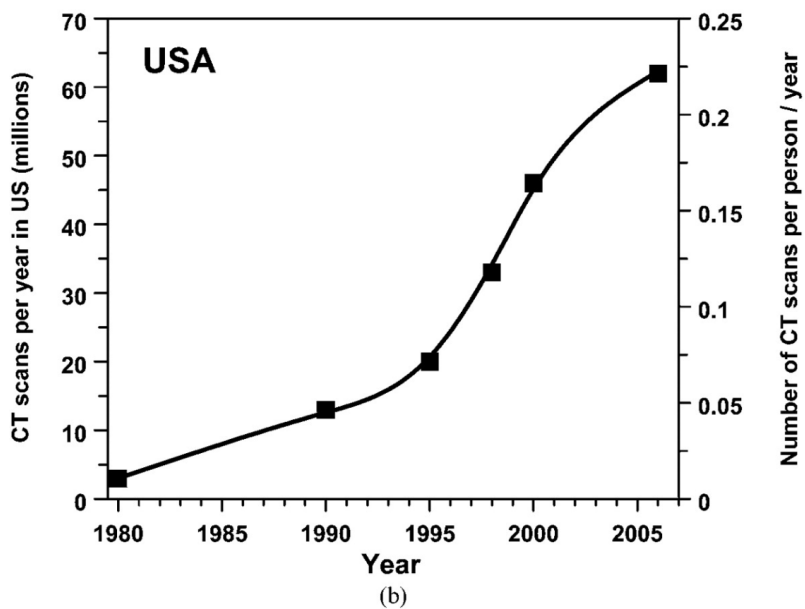
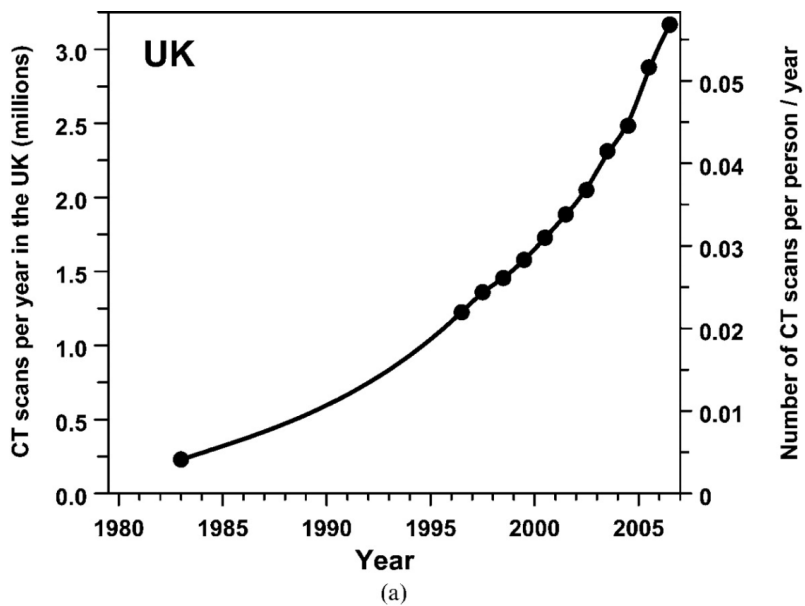


Figure 2. Graphs illustrating the rapid increase in the number of CT scans per year in (a) the United Kingdom and in (b) the United States, as well as the number of CT scans per person/year (22).

Besides the volume increase, there have been significant shifts in how different modalities are used (23-30). From 2002 to 2008, the annual number of MRI and CT imaging procedures per capita in Norway both doubled, while there was a corresponding decrease in conventional x-ray examinations, and to some degree, in US examinations (13).

The availability of scanners and the volume of medical imaging can vary extensively from country to country (Figure 3 and 4) and within different parts of one country. In 2004, Norway had 27 CT scanners per 1 million inhabitants, as opposed to six scanners per 1 million inhabitants in the United Kingdom (31). CT is used five times more per capita in the United States than in the United Kingdom (Figure 2) (22), while on the other hand, medical imaging is hardly accessible at all in many health care level IV countries. In Norway, the use of medical imaging varies with a factor of 2.3, comparing the capital region of Oslo to the more rural areas of northern Norway (32). These variations are hardly correlated to variations in disease prevalence, and to some degree they indicate either overuse or underuse of medical imaging.

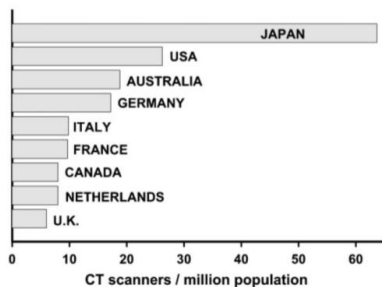


Figure 3. Number of CT/MSCT scanners per million population in selected countries in the 1990s. Data from a 1991–1996 survey reported by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (33).

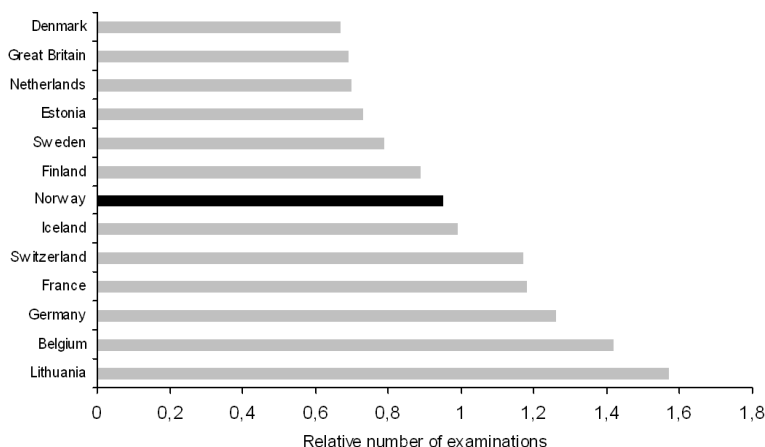


Figure 4. Relative number of examinations per 1,000 inhabitants for some European countries (13).

The changes in how medical imaging is used do not necessarily reflect evidence-based practice. The technology itself is developing at such a pace that new, attractive and impressive techniques are implemented and taken into use before their utility and evidence-based cost-effectiveness are established (34;35).

The increased use of x-ray-based medical imaging has caused a marked increase in the radiation dose to the patient population (14;36) and this has concerned physicians and radiation physicists, as well as regulatory bodies and politicians. The regional variation in the use of imaging also implies a variation in mean annual effective dose per capita by up to a factor of 60 between health care level I and IV countries, and by a factor of about 6 within health care level I countries (14;37;38).

The large and varying volumes of imaging and the related radiation exposure have intensified the question of justification. To what degree is the imaging performed and the dose burden inflicted on the patients justified? Beyond radiation issues, economical questions and the priority of health resources call for justification to be considered. A Swedish study estimated that 20% of all MSCTs performed in Sweden may not be justified (39), in concordance with other works on unjustified imaging (40;41).

Knowing the radiation doses from different imaging procedures and the risks of detrimental effects is necessary in order to be able to decide whether the benefits of an examination outweigh its costs; in other words whether the

examination is justified or not. Several studies have revealed a lack of radiation knowledge among different groups of physicians (42-53).

A possible way to overcome the problems of practice that is not evidenced-based and lack of radiation knowledge is, to develop evidence-based referral guidelines, stating what to refer to in given clinical conditions. Such guidelines have been developed by the Royal College of Radiologists in the United Kingdom (54), the European Commission (EC) (55) and the American College of Radiology (56). The EC guidelines have been translated into Norwegian (57), and may help in the process of justifying imaging procedures (58).

3.3 Patient radiation doses

3.3.1 Radiation biology and risk considerations

As the name implies, ionizing radiation can penetrate tissue and ionize atoms within the organism. Alpha particles, beta particles, neutrons or electromagnetic waves can cause tissue damage through free radicals or direct damage of deoxyribonucleic acid (DNA) (59;59). Another possible way of inducing detrimental effects is by the so-called bystander effect (60).

Deterministic effects of ionizing radiation are due to the killing of cells or induction of severe malfunction in cells following high doses, and occur only at doses above a certain threshold. Deterministic effects are to some extent proportional to the dose given. The radiation doses from medical diagnostic procedures are usually far below this threshold, but deterministic effects such as skin burns and hair loss have been reported after fluoroscopic interventional procedures (61) and extensive stroke-imaging on MSCT (62). Other examples of deterministic effects are sterility, cataract, bone marrow depression, fetus abnormalities, killing of tumor cells as desired in radiation therapy (63), acute radiation syndrome with hematological, gastrointestinal and neurological affection and ultimately death following radiation exposure (64).

Stochastic radiation effects are either cancer due to mutation of somatic cells, or heritable disease in the offspring due to the mutation of germ cells. Modified cells may develop into cancer after a latency period of decades. In principle, stochastic effects are assumed to have no threshold. They do not occur with certainty, but the exposed individual has a higher statistical chance of developing, for example, cancer. The doses given by the diagnostic procedures might cause stochastic effects, and the probability increases with the magnitude of the doses.

Data from the Life Span Study (LSS) of atomic bomb survivors of Hiroshima and Nagasaki constitute the “gold standard” in assessment of the carcinogenic risk of low radiation doses. The LSS show evidence for biological detrimental effects from doses in the magnitude of 35mSv, consistent with a linear relationship between cancer risk and radiation dose (Figure 5) (65;66). A 15-country collaborative study of 400,000 radiation workers in the nuclear industry, exposed to a lower mean dose of 20mSv, showed a statistically significant increased cancer risk, concurring with the LSS findings (67).

The dose-response relationship of doses in the magnitude of 0-30mSv is still dependent on extrapolations from larger doses and has been intensely debated (68). Providing evidence for detrimental effects of such small doses is a demanding task, requiring large study populations and long follow-up periods. Looking at about 8,000 cardiac patients, Eisenberg et al found a dose-dependent association between radiation exposure from cardiac procedures and subsequent risk of cancer in the range of 0-30 mSv (69), while Doody et al found an increased breast cancer rate in female scoliosis patients receiving a mean cumulative dose of 10.8 cGy to the breasts (70). The EC recently initiated a large-scale multinational collaborative study to directly evaluate radiation-related risk of cancer following MSCT. It is planned to include over 1 million children in the study (71).

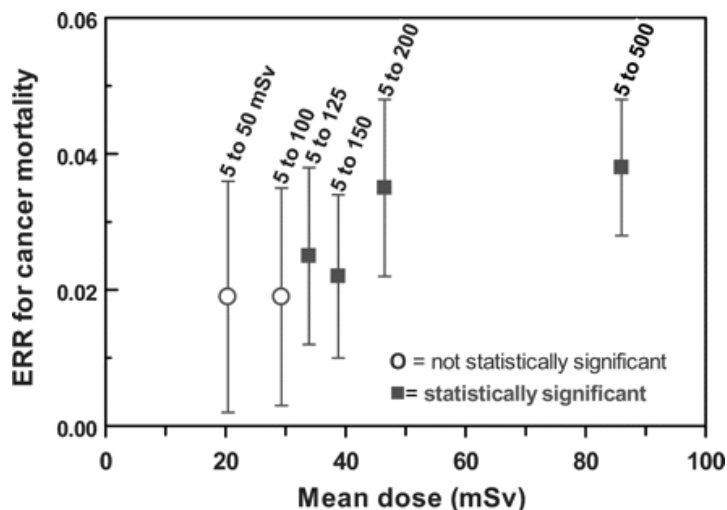


Figure 5. Estimated excess relative risk (ERR) \pm 1 standard error of solid cancer mortality among LSS cohorts (22). The dose groups correspond to progressively larger maximum doses, with the ERR plotted against the mean dose in each group. For instance, looking at the group exposed to 5-200mSv, they had a 3.5% greater risk of developing cancer than non-exposed individuals.

Supported by the data mentioned above, the linear-non-threshold theory (LNT-theory), implying no dose threshold for inducing stochastic effects and a linearity between dose and increased cancer risk, is the basis for all international work and institutions dealing with radiation protection (65;68). The LNT-theory, regarded as prudent and conservative by many(72), implies that doses received at different times are added, that doses received from one source should be considered independently of doses received from other sources, and that radiation exposure even at very small doses includes some risk.

When it comes to quantitative assessments of increased cancer risk due to a given radiation dose, a fatal risk coefficient of 0.5% per Sv (about 1 fatal cancer per 2000 abdominal CT scans of 10 mSv) is estimated by the International Commission on Radiation Protection (ICRP) (sex averaged, time-at-exposure averaged and averaged across Asian and European-American populations (73). The implications of this risk estimate are modeled in Figure 6 by the Committee on Biologic Effects of Ionizing Radiation (BEIR).

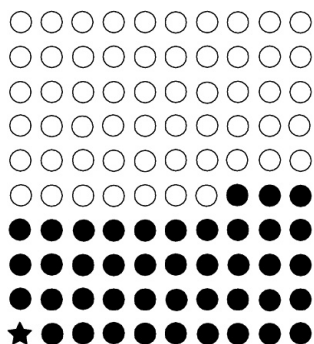


Figure 6. In their lifetime, approximately 42 (solid circles) out of 100 people will be diagnosed with cancer. The risk estimates of BEIR VII suggest that approximately one cancer (star) would result if these 100 persons were exposed to 0.1Sv of low linear energy transfer (LET) radiation above background radiation(59).

Berington de Gonzales and Darby estimated cancer risk from diagnostic x-rays use in the years 1991 and 1996 for the United Kingdom and 14 other countries, and estimated that about 0.6% of the accumulated risk of cancer at the age of 75 could be attributable to diagnostic x-rays. This was equivalent to about 700 cases of cancer per year in the United Kingdom and 77 in Norway respectively (74).

The radiation induced cancer risk is age- and sex-dependent. Female individuals are more radiosensitive than males. In children, cells are dividing to a greater extent than in full grown persons, and this makes them biologically more susceptible to stochastic effects. Together with a longer time span to develop a radiation-induced cancer, this makes them more vulnerable to ionizing radiation (59;75). The sex-difference and increased radio sensitivity of children is illustrated in Figure 7.

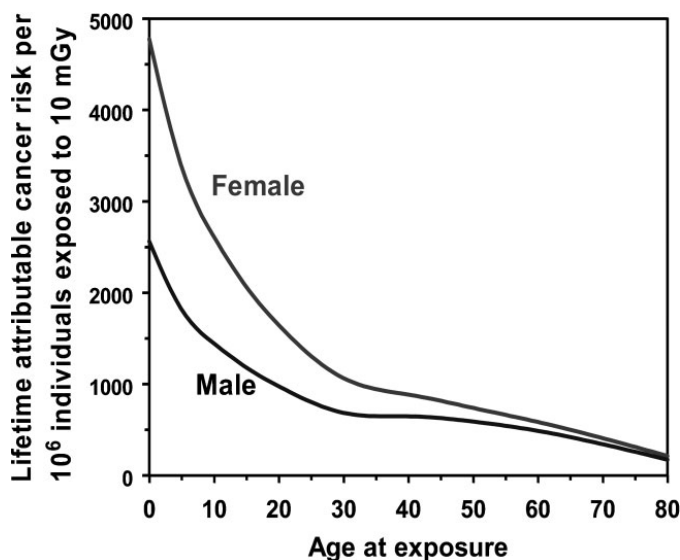


Figure 7. Estimated lifetime attributable risk (LAR) from a single small dose of radiation as a function of age at exposure (22). Note the sex difference and dramatic decrease in radio sensitivity with age. For instance, 1,000 of all cancer incidents during the lifetime of 10^6 males, exposed to 10mGy at the age of 20, would be attributable to this radiation exposure, while this number would be nearly 2,000 for 5-year-old males.

Opposing the LNT-theory, several researchers believe in the process of hormesis (72;76). This hypothesis states that small amounts of radiation induce an adaptive response and stimulate biological defense mechanisms, thus protecting the cell from detrimental effects of radiation and actually reducing the incidence of cancer. Other alternatives to the LNT-theory is a linear dose-response relationship; however with a threshold for stochastic effects, or different non-linear relations (Figure 8).

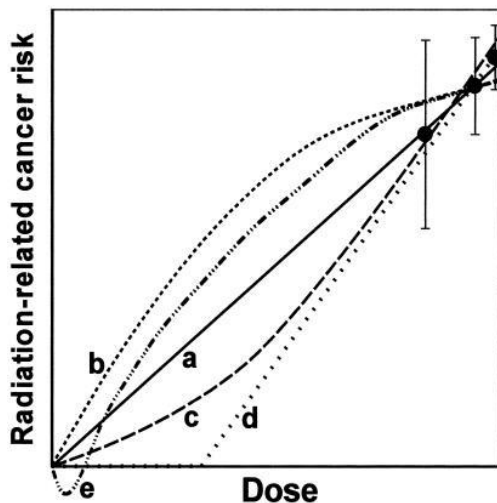


Figure 8. Schematic presentation of different possible extrapolations of measured radiation risks down to very low doses, all of which could, in principle, be consistent with higher-dose epidemiological data (65). Curve a, linear extrapolation; curve b, downwardly curving (decreasing slope); curve c, upwardly curving (increasing slope); curve d, threshold; curve e, hormetic.

3.3.2 Dose concepts in radiation protection

The possible biological influence of ionizing radiation depends on the energy absorbed per unit mass in a given tissue or organ. This fundamental physical quantity, called the *absorbed dose*, is expressed in Gray (Gy), and is defined as

$$D = d\bar{\epsilon} / dm$$

where $d\bar{\epsilon}$ is the mean energy imparted to matter of mass dm by ionizing radiation. One Gray equals 1 joule of radiation energy absorbed per kilogram. To be able to adjust for various radiation types' effectiveness in terms of stochastic effects, the quantity of the *equivalent dose*, H_T , is introduced and expressed as:

$$H_T = \sum_R w_R D_{T,R}$$

where w_R is the radiation weighting factor for radiation R (1 for x-rays and electrons, 2 for protons, 20 for alpha particles). $D_{T,R}$ is the average absorbed dose in a volume of a specified organ or tissue T , due to radiation R .

When evaluating the radiation risk after partial exposures of the body, the radio sensitivity of various organs (tissue-weighting factors) has to be taken into consideration, and then the quantity of *effective dose* is applied (73). Effective dose, E, reflects the risk of detrimental biologic effects (carcinogenesis, life-shortening and hereditary effects) from non-uniform, partial body exposure in terms of whole-body exposure (77), and is described in the equation:

$$E = \sum_T (w_T w_R D_{T,R}), \text{ or } E = \sum_T w_T H_T$$

where w_T the tissue weighting factor, w_R is the radiation weighting coefficient, $D_{T,R}$ is the average absorbed dose in tissue T, T is the subscript for each radiosensitive tissue, and R is the subscript of each type of radiation. H_T is the equivalent dose. The weighting factors are set for each organ in Publication 103 of the ICRP (Table 1).

Tissue	w_T
Bone-marrow (red), colon, lung, stomach, breast, remaining tissues*	0.12
Gonads	0.08
Bladder, esophagus, liver, thyroid	0.04
Bone surface, brain, salivary glands, skin	0.01

*Adrenals, extra thoracic region, gall bladder, heart, kidneys, lymph nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus, uterus/cervix

Table 1. ICRP 103 tissue weighting factors for calculation of effective dose (73).

The unit for effective dose is the sievert (Sv). The way effective dose is calculated makes it an approximate estimate of the true risk for a “mean” individual, and allows for a rough comparison between different examinations (78). For a reference patient, the uncertainty is estimated to $\pm 40\%$. For risk estimation on an individual basis, age, sex, body mass and differences in genetic susceptibility to cancer induction introduce an element of uncertainty to these calculations that is much greater (78). Due to its inherent uncertainties and oversimplifications, the effective dose should not be used for detailed specific retrospective investigations of individual exposure and risk. When assessing the total radiological exposure to a group of people, the term *collective effective dose* (CED) is used, and CED is obtained by multiplying the mean effective dose to the members of the group by the number of people in the group:

$$S = \sum_i E_i N_i$$

where E_i is the average effective dose for a group, and N_i is the number of individuals in this group. The unit for CED is the manSievert (manSv). CED is an instrument of optimization, for comparing radiological technologies and protection procedures, including diagnostic medical and occupational exposure. The relation between these different quantities is shown in Figure 9.

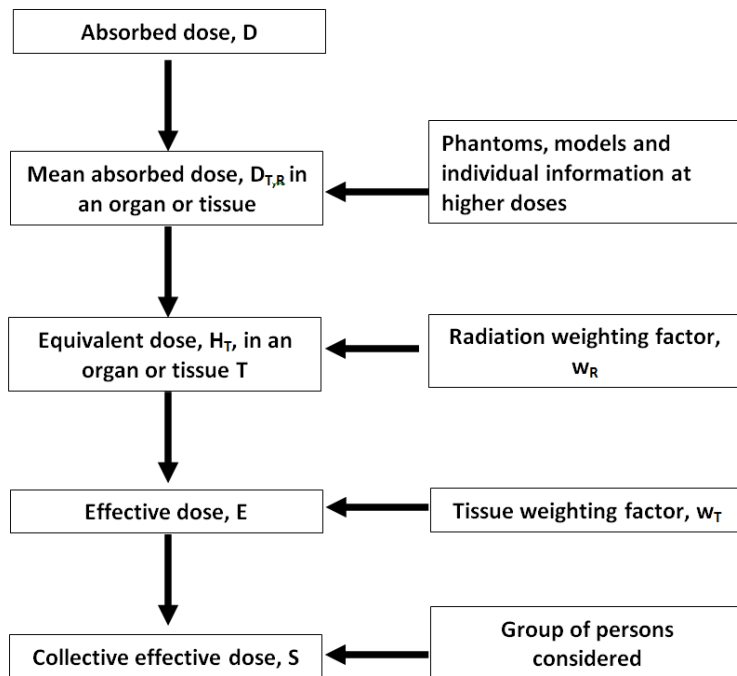


Figure 9. System of dose quantities for use in radiological protection (73).

3.3.3 Practical dose quantities

The most convenient method for real time dose monitoring in conventional radiological examinations and fluoroscopy is based on the dose area product (DAP), also called the Kerma area product (KAP) (31). The DAP is the product of the surface area of the patient that is exposed at skin entrance, and the radiation dose at this surface, expressed in Gy x cm². Modern x-ray systems are fitted with a plane-parallel ionization chamber intercepting the entire x-ray beam. This can record the accumulated DAP during an examination. By means of established conversion coefficients, assessment of organ doses and effective doses may be made.

The entrance surface dose (ESD) is a less used approach for monitoring doses, but for certain interventional procedures(31), knowledge of ESD may be essential as a precaution against deterministic effects.

A fundamental dosimetric quantity for CT is the CT Dose Index (31) measured free in air (CTDI_{air}). CTDI_{air} is the integral of the absorbed dose to air profile along the axis of rotation of the CT scanner, for a single rotation, divided by the total nominal detector collimation in the longitudinal direction (equals the nominal slice thickness for single slice scanners). Units: mGy.

In the European Guidelines on Quality Criteria for Computed Tomography (79), diagnostic reference dose values are indicated for two CT dose descriptors: weighted CTDI (CTDI_w) and dose-length product (DLP). CTDI_w is the weighted sum of the CTDI measured in the center (c) and periphery (p) of a 16 cm (head) or a 32 cm (trunk) diameter cylindrical phantom. Units: mGy

$$CTDI_w = 1/3 CTDI_c + 2/3 CTDI_p$$

CTDI_w provides an indication of the average absorbed dose in the central slice of a series of contiguous scans of the phantom.

Volume CT dose index (CTDI_{VOL}) is the CTDI_w corrected for the CT pitch factor. The CT pitch factor is the ratio between the table feed and the product of the number of slices and the collimation of a single slice in mm. Units: mGy

$$CTDI_{VOL} = CTDI_w / \text{pitch factor}$$

CTDI_{VOL} provides a rough indication of the average absorbed dose over the scanned volume in the patient.

CT Dose-length product (DLP): DLP is the product of the $CTDI_{VOL}$ and the total scan length along the patient in the axial direction for a particular CT examination. Units: mGy cm.

The International Commission on Radiation Units and Measurements (ICRU) has also introduced the units CT air kerma index (CKI) instead of CTDI and air kerma-length product (PKL) instead of DLP (80). The ICRU considers the use of the term *air kerma* to be more appropriate than *absorbed dose or dose*, because this quantity is in fact the quantity measured in practice. For diagnostic x-ray energies, the absorbed dose and the kerma in the same material are numerically equivalent, thus, the new recommendations of ICRU would practically not imply any changes in measurements. However, most recommendations and CT scanners still use the units CTDI and DLP.

The effective dose from a CT examination can be quite simply calculated from DLP using appropriate normalized coefficients relating to the region scanned:

$$E = E_{DLP} DLP,$$

where DLP is the length product and E_{DLP} is the region specific normalized effective dose coefficient (79). However, the gold standard for calculating effective CT doses is to calculate organ doses based on Monte Carlo simulations (81). These simulations account for different scanners, their geometry and protocol specific parameters such as tube potential and current, beam collimation, CTDI and scan length, and are based on a mathematic 208 axial 5mm slab phantom. Simulating a scan, doses to organs located in the irradiated slabs are calculated, and total organ doses can be estimated. Practically, such calculations can be done with a freely available spreadsheet from The ImPACT Group (82).

3.3.4 Magnitude of radiation dose

Typical radiation doses from different diagnostic imaging procedures are given in Table 2. Radiation doses from conventional radiological examinations are usually small, compared to MSCT imaging, interventional procedures and fluoroscopic examinations. MRI and US examinations imply no ionizing radiation.

Procedure	Average effective dose of radiation (mSv)	Equivalent number of radiographs	Equivalent period of average natural background radiation (days)
Posteroanterior chest radiography	0.02	1	3
Skull radiography	0.1	5	15
Mammography	0.4	20	61
Pelvic radiography	0.6	30	91
Abdominal radiography	0.7	35	106
Lung perfusion scintigraphy (99mTc-MMA)	2	100	304
CT brain	2	100	304
Intravenous urography	3	150	456
Bone isotope scintigraphy (99mTc-MDP)	6.3	315	958
CT chest	7	350	1065
CT abdomen	8	400	1217
Barium enema	8	400	1217

Table 2. Average effective doses of radiation for various diagnostic radiology procedures (83).

The radiation dose from one particular imaging procedure can vary extensively from one institution to another due to differences in image quality standards, equipment, protocols and practice. When collecting 383 local representative doses (LRD) in the years 2006-2009 Friberg et al (84) found great variations in local representative doses in Norway. For abdominal/pelvic CT, the mean LRD was 635 mGycm with a maximum / minimum ratio of 6.8. Large variations in doses for given MSCT examinations were also demonstrated by Smith-

Bindman et al (85), showing a mean 13-fold variation between the highest and lowest dose for each study type.

Radiation doses from some imaging procedures have decreased during the last years due to technological developments and optimization work. From 2002 to 2008, the Norwegian average effective dose for CT abdomen decreased from 12.6mSv to 10 mSv, chest CT from 11.5 to 4.7 mSv and pelvic CT from 9.3mSv to 7.3mSv (13).

The imaging procedures contributing most to the Norwegian CED in 2008 were abdominal MSCT (1687 manSv), pelvic MSCT (858 manSv), chest MSCT (554 manSv) and cerebral MSCT (262 manSv) (13). Fazel et al, looking at a population of almost one million in the years 2005-2007, found myocardial perfusion imaging, abdominal, pelvic and chest MSCT and diagnostic cardiac catheterization to be the top five contributors to the CED in United States (86).

Comparing medical imaging to other sources of radiation, an average Norwegian is exposed to about 5 mSv per year in total. Radon is the largest source with 3 mSv, while medical imaging contributes with 1.1 mSv and natural gamma background radiation 0.5 mSv (Figure 10) (84). In the United States in 2009, an average American was exposed to 5.6 mSv, medical imaging contributing 3.0 mSv, and natural background radiation 2.4 mSv (14).

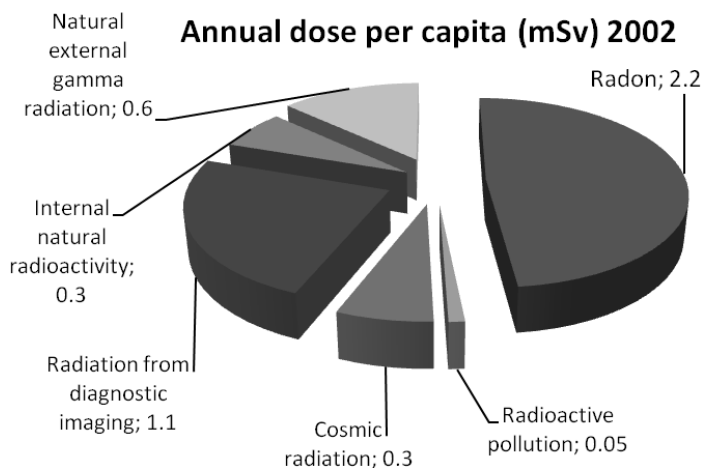


Figure 10. Contributors to the annual radiation exposure of an average Norwegian (84).

Thus, radiation protection, particularly because of the possible detrimental effects of ionizing radiation from MSCT (87;88), has become a major issue in radiology (86;89;90) and the crucial question is to what extent patient radiation exposure from medical imaging is inducing cancer (74;91). The focus has changed, from multiple detectors and “breath-taking” images to dose reduction and good enough image quality (92), from “slice wars to dose wars” (89).

Radiation protection issues were brought to public attention and lifted to a political level in the United States during 2009, through the Food and Drug Administration (FDA) investigation of stroke patients receiving large radiation doses, and through congress hearings. One exposed patient has filed a class-action law suit against GE Healthcare (93). In the wake of these cases and others, the new Californian Radiation Overdose Bill was ratified in 2010 (94).

The CED from medical imaging has increased during recent decades in developed countries. In Norway, during the years 1993 to 2002, the CED increased by 40% to 4960 man Sv (95), while the increase from 2002 to 2008 was 237 manSv (5,6%) (13). CT contribution to the 2008 Norwegian CED was 79%, compared to 66% in 2002 and 30% in 1993. Compared to other European countries, the relative contribution of CT to the national CED in Norway is among the highest (13). A working group of the network of Heads of European Radiation Control Authorities recently looked at the CED from the 20 largest examination contributors in 13 European countries. The CED from these “TOP 20” examinations varied from 331 – 1521 mSv per 1000 population, CT contributing 46-81%. On average, there was an increase of 12% in the CED from around 2002 to 2008 (96). In the United States, the CED from medical imaging was 899.000 manSv in 2006, rising from 124.000 manSv in 1980, MSCT scanning accounting for 49% of the 2006 CED (14).

3.4 Radiation protection

3.4.1 Definitions

The ICRP defines three principles of radiological protection (73):

1. The Principle of Justification: Any decision that alters radiation exposure should do more good than harm.

2. The Principle of Optimization of Protection: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should be kept as low as reasonably achievable, taking into account economic and societal factors.
3. The Principle of Application of Dose Limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

3.4.2 Justification

According to the ICRP, the principle of justification for medical procedures applies at three different levels. At the first level, the use of radiation in medicine is accepted as doing more good than harm to the patient, and this level is taken for granted. At the second level, a specific procedure with a specific objective is defined as justified (e.g., chest radiographs for patients showing certain symptoms) and this level of justification is a matter for national and international bodies, in conjunction with national health and radiological protection authorities and the corresponding international organizations. At the third level, the application of a procedure to a certain individual should be justified (e.g., a particular CT examination should be judged to do more good than harm to a certain individual). This implies that the relevant medical practitioners need to take into account the details of the proposed procedure and of alternative procedures, the characteristics of the individual patient, and the expected dose to the patient.

3.4.3 Optimization

The process of optimization is intended for application to those situations that have been deemed to be justified. When deciding that an imaging procedure is justified, it should be done in such a way that the image quality and thus clinical information are sufficient, while the radiation dose is kept as small as possible. This concept is known as the ALARA-principle – to keep the doses “As Low As Reasonably Achievable”. Optimization applies at two levels: 1) the design, appropriate selection, and construction of equipment and installations; and 2) the day to day methods of working (i.e. the working procedures) (97).

3.4.4 Dose limits

The principle of dose limits applies on planned exposure situations to workers and the public, but does not apply to medical exposure of patients, as dose

limits could be counterproductive to the medical purpose of the procedure. For occupational exposure (i.e. radiologists or radiographers), the limit is expressed as an effective dose of 20mSv per year, averaged over five years, and the dose should not exceed 50 mSv in any year. For public exposure, the annual limit is 1 mSv.

3.4.5 Optimizing tools

The local representative dose (LRD) (98) is the mean dose for a particular examination at a particular institution and is based on 20 patients of normal body weight. The LRD contributes to the national dose reference level (DRL), but is also a local optimizing tool, enabling institutions to compare their own practice to other institutions and to the national DRL.

The concept of DRL (98;99) is established as guiding the dose level for a given examination and hence is an important optimizing tool. The DRL of an examination applies to groups of similar patients, rather than to individuals, and is used to ensure that doses do not deviate significantly from those achieved at peer departments unless there is a valid reason for it (100). DRL reflects the 75 percentile of the mean dose on a national level and is revised periodically. Institutions exceeding the reference dose are advised to take optimizing action. Through continuous optimization, the reference dose will inherently decrease for every revision.

An aspect of applying the ALARA principle is to choose a non-radiation based imaging modality whenever practical for a given condition. Using US may be an alternative to CT, for instance when following the course of kidney trauma (101), and using MRI instead of CT may be an alternative when imaging the spine or a pancreatitis patient (102). Choosing MRI or US, rather than a radiation-based modality is especially important for pediatric patients (103), and for fertile or pregnant women.

There are several ways to optimize a CT protocol (104;105). Firstly, what diagnostic information is needed and what are the corresponding requirements of image quality? If looking for urinary stones, non-enhanced low-dose protocols will be sufficient. Limiting the scan length and number of contrast phases (106;107) are other ways to limit radiation exposure. Several parameters of the acquisition can be optimized, such as by adjusting the tube current (mA) directly (108;109) or through automatic tube current modulation (110-112). Further parameters to be optimized are kV (113-115), pitch (116) and collimation (116). Bowtie filters and bismuth eye- and breast-shields are other optimizing tools (117). Having carried out the acquisition, there are

different ways to post process and restore images. Two-dimensional (2D) post-processing filters are commercially available, and several authors have evaluated such filters using phantom images (118-122) and clinical images (123-128). Three-dimensional (3D) filters, either operating in the raw data domain or in the spatial domain (i.e. post-processing), are at an early stage of development (129;130), but the clinical benefits of this type of filter are expected to be even greater than those of 2D filters. A comparison of 2D and 3D filter effects has been published for the US modality (131), but not for CT.

Systematic radiation protection work over the years, continuously introducing new optimizing technology, may reduce the patient dose substantially (106;132;133).

A powerful optimizing tool that has come into use recently is iterative reconstruction (134-137). Compared to the traditionally used filtered back projection, iterative reconstruction uses a forward reconstruction model and implies a more precise modeling of scanner geometry and the underlying physics, while also being more robust to insufficient data and artifacts. Iterative reconstruction allows for considerable dose reduction and has been adopted by all major CT vendors; adaptive statistical iterative reconstruction (ASIR) by GE Healthcare (138), iterative reconstruction in the image space (IRIS) by Siemens Medical Solutions, adaptive iterative dose reduction (AIDR) by Toshiba Medical Systems and iDose by Phillips Healthcare.

3.5 Assessment of image quality

Image quality can be assessed objectively by physical measures and subjectively by readers for a direct evaluation of clinical information. Physical measures include parameters such as detective quantum efficiency (DQE), which describes to what extent the system is able to interpret available data, the modulation transfer function (MTF), which describes how well the signal strength (contrast) is kept in the system, the noise power spectrum (NSP), which describes the contributions of different spatial frequencies to the total noise, image resolution, the signal to noise ratio (SNR), the contrast to noise ratio (CNR), Hounsfield units (HU) and noise in terms of standard deviation of HU values. The correlation between objective and subjective image quality is not always straightforward, and subjective evaluation of images remains an important optimization task (139;140).

Assessing the clinical image quality, receiver operating characteristics (ROC) studies (141;142) represents the gold standard. Key features of ROC studies are that they relate to the detection of pathology and that they are able to

evaluate different imaging systems, excluding the effect of the individual observer's threshold for detecting a lesion. ROC studies are usually expensive and time consuming; therefore visual grading analysis (VGA), often related to EC image criteria (143), may be performed. The EC image criteria define anatomical structures to be sharply reproduced, the underlying assumption being that a sharp reproduction of normal anatomy implies sharp reproduction and depiction of pathology. Aspects of VGA as well as ROC have been combined in the method of visual grading characteristics (VGC) (144). Visual grading regression (VGR) is another related statistical method (145).

3.6 Scientific and regulatory bodies, legal framework

Various organizations and entities continuously evaluate radiation risks and provide guidance and recommendations on radiation protection matters covering the whole range of applications of ionizing radiation.

3.6.1 The International Commission on Radiation Protection

As the use of x-rays for medical purposes rapidly evolved after their discovery in 1895, the potential hazards of X-rays were also soon recognized. The International Commission on Radiation Protection (ICRP) was created in 1928, as a Commission linked to the International Congress of Radiology. Today, the ICRP is an advisory body offering its recommendations to regulatory and advisory agencies. While the ICRP has no formal power to impose its proposals on anyone, in fact legislation in most countries adheres closely to ICRP recommendations. The ICRP publishes its recommendations through its own publications, the Annals of the ICRP. Concerning radiological protection in medicine, the two most important annals issued recently are The 2007 Recommendations of the International Commission on Radiological Protection, ICRP publication 103 (73), and Radiation protection in medicine ICRP Publication 105(97). The ICRP has also issued publications on radiation and pregnancy (146), interventional procedures (147), MSCT (148), radiation therapy (149) and brachytherapy (150).

3.6.2 European Commission

Through its Council Directive 96/29EURATOM (151) and Council Directive 97/43EURATOM (152), the European Commission (EC) defines requirements on justification, optimization, reference doses, dose assessments, patient records, quality control, education, responsibilities etc. Requirements and recommendations for education in radiation knowledge and protection are also developed within the EC (153). The EC has organized a series of workshops within diagnostic radiology, generating essential information for the establishment of the EC quality criteria for diagnostic radiographic imaging in pediatrics (154), adult radiographic imaging (155) and MSCT imaging (79), and providing an operational framework for radiation protection initiatives. Even though Norway is not a member of the European Union, the Norwegian legislation is mostly harmonized with the legal framework of the European Community, and Council Directive 96/29EURATOM and 97/43EURATOM have a major influence on Norwegian national legislation on radiation

protective issues.

3.6.3 The Norwegian Radiation Protection Authority

The Norwegian Radiation Protection Authority (NRPA) is the competent national authority in the area of radiation protection and nuclear safety in Norway. The NRPA is responsible for overseeing the use of radioactive substances and fissile material, monitoring natural and artificial radiation in the environment and in the workplace, and increasing our knowledge of the occurrence, risk and effects of radiation. The NRPA is organized under the Ministry of Health and Care Services. It provides assistance to all ministries, including the Ministry of Foreign Affairs and the Ministry of the Environment on matters dealing with radiation, radiation protection and nuclear safety.

3.6.4 Norwegian law and regulations

The Law of Radiation Protection was ratified in the year 2000 (156), replacing the “X-ray law” of 1938. The Law of Radiation Protection has a broader focus and also regulates environmental issues, including ionizing and non-ionizing radiation. The first regulations of the law came into effect in 2003. These define the need for authorization to use ionizing radiation, set qualification standards for people working with radiation, and regulate professional exposure and person dosimetry. Chapter VII of the regulations deals with medical use of radiation, and focuses on justification and optimization. The most recent regulations introduced under the Law of Radiation Protection were ratified in 2010, putting even more focus on the justification of medical imaging (157). The regulations do not go into detail, hence the NRPA has developed Guidance Paper No 5 (98) about medical use of x-rays and MRI, which gives practical guidance on how to comply with the law and its regulations.

3.6.5 Other international bodies

The World Health Organization (WHO) acts as a directing and coordinating authority on international health work within the United Nations system. WHO evaluates health risks related to radiation exposure and provides advice to national authorities. WHO provides support in the case of nuclear or radiological accidents, assists in building national capacity, and reinforces information and education on radiation protection issues (158).

The United Nations Scientific Committee on the Effects of Atomic Radiation (USCEAR) systematically reviews and evaluates global and regional levels and

trends of medical exposure, exposure of the public and workers, as well as the evidence for long-term health effects from the atomic bombings in Japan in 1945(159).

The International Atomic Energy Agency (IAEA) is an independent intergovernmental, science and technology-based organization within the UN family, and assists its Member States in developing and using nuclear science and technology for various peaceful purposes. IAEA publications provide recommendations on patient safety and radiation protection, practical recommendations on the establishment of guidance levels for diagnostic medical exposures, the calibration of radiotherapy units and the reporting of accidental medical exposures (160).

In the United States, the National Research Councils' Committee on Biologic Effects of Ionizing Radiation (BEIR) reviews and evaluates the current knowledge on the biologic effects of ionizing radiation. The last report, BEIR VII (59), focuses on health effects of low levels of linear energy transfer (LET) ionization radiation (including x-rays and gamma-rays), and gives support to the LNT-theory.

4. Aims of the Study

The development of medical imaging as described above has turned radiation protection into a principal concern of today's radiology. The main principles of radiation protection - justification and optimization - are fundamental to ensuring a safe and meaningful use of radiology. Through 1) descriptive retrospective historical studies on modality shifts and changes in radiation doses, 2) a questionnaire on clinicians' radiation knowledge and awareness in relation to their justification of imaging, and 3) a prospective double blinded study exploring measures to reduce radiation doses, the papers of this thesis address radiation protection issues from different angles and with different methodologies. These are the study aims:

- Papers I and II investigate the extent of modality shifts and their impact on radiation doses from 1979-2003. When imaging the organ system of the urogenital tract (paper I) and the spine (paper II) during this time period - how did the introduction of US and later MRI for urogenital tract examinations, and CT and later MRI for spine examinations, together with the utilization of a radiation protection policy, influence the collective dose from ionizing radiation to patients referred to the Department of Radiology at a county hospital? We hypothesized that the introduction of non-x-ray-based modalities and a radiation protective policy would be able to reduce the collective radiation dose while

maintaining or increasing the total number of examinations of these organ systems.

- Paper III investigates the justification process of medical imaging in a cross-section study on current referral practice, radiation knowledge and attitudes. Through a questionnaire we explored general practitioners', hospital physicians', and non-physicians' 1) radiation knowledge, 2) weighting of radiation dose when referring, 3) use of referral guidelines, 4) rate of and reasons for referrals unlikely to affect treatment, and 5) whether this rate and the guidelines used are related to the clinicians' radiation knowledge and weighting. We hypothesized that clinicians who put less emphasis on radiation issues use referral guidelines less often, and are more likely to order imaging that is unlikely to affect treatment.
- The overall aim of the study presented in paper IV is to reduce radiation exposure caused by MSCT to the patient population. The study addresses the issue of optimization through a double blinded prospective study of a novel optimizing tool for MSCT imaging. We hypothesized that a 3D post-processing filter would be able to restore abdominal MSCT images acquired with a 50% dose reduced scan to the quality of full dose images. We also hypothesized that a 3D post-processing filter is more effective in restoring low dose images than a 2D post-processing filter.

5. Material and methods

Paper I and II. Activity reports within the Department of Radiology at Drammen Hospital on numbers and types of examinations of the spine and urinary tract over a period of 25 years have been studied. Paper I investigates the use of plain radiographs, intravenous pyelography (IVP), CT, US and MRI examinations of the urogenital tract, while paper II investigates the use of conventional radiographs, myelography, CT and MRI examinations of the spine. Dose figures from specific examinations are based on dose registrations from several Norwegian hospitals in the period 1980 – 1990 (161).

Paper III. A questionnaire was distributed to 213 unprepared Norwegian clinicians, 77 general practitioners, 71 hospital physicians and 65 non-physicians. The questions concerned weighting of radiation dose, guideline use, referrals unlikely to affect treatment, doses from imaging procedures, ranking of imaging as a radiation source, and deterministic and stochastic effects.

Paper VI. Full dose and 50% dose-reduced MSCT images of the upper abdomen were acquired from 12 study patients. Low dose images were post-processed with 2D and 3D non-linear adaptive filters. Image quality, comparing normal dose, low dose, 2D- and 3D-filtered images, was subjectively evaluated by six radiologists doing a pair wise comparison. Absolute CT numbers and noise in terms of standard deviation of CT numbers were measured.

6. Summary of Results

6.1 Paper I

The total number of x-ray-based examinations of the urinary tract decreased from 1,831 in 1979 to 1,114 in 2003, especially for the IVP. The total number of non-x-ray-based examinations increased from 0 in 1979 to 1,428 in 2004. Starting with 8 examinations in 1983, US was performed 1,388 times in 2003. MRI was introduced in 1994 with three examinations and was performed 40 times in 2003. The total number of examinations, including x-ray-based and non-x-ray-based, increased from 1,831 examinations in 1979 to 2,542 in 2003, and US and MRI gradually replaced x-ray-based examinations.

The shift in modalities from 1979 to 2003 had a significant impact on the radiation doses given to this patient population. In spite of an increase in the total number of investigations, there was a reduction in radiation doses. The 1979 CED was 6.0 manSv, decreasing to 3.7 manSv in 2003. The radiation dose per examination, regardless of modality, decreased from 0.0033 manSv to 0.0015 manSv during this period.

6.2 Paper II

The number of conventional x-ray examinations of the spine increased from 2,858 examinations in 1979 to 4,179 in 1993. Thereafter, the number decreased to 2,150 in 2000, finally reaching 2,697 in 2003.

The number of myelographies almost doubled from 284 examinations in 1979 to 506 in 1990. From 1990 there was a decrease, and this accelerated from 1993. The number of examinations in 2003 was seven. The number of CT examinations increased from 10 examinations in 1979 to 675 in 1993. After 1993, the trend showed a rapid decrease in examinations as with myelography. In 2003, 128 CT examinations were performed.

MRI was introduced in 1992. In 1993 a rapid increase in the number of MRI examinations started, the number being 34 in 1993 and 2,483 in 2003. The shift of modalities was significant for the vertebral column as a whole, and particularly for the lumbar region. Myelography had its “top year” in 1990, and was to a certain extent replaced by CT. CT reached its maximum in 1993, then partially replaced by MRI.

The shift in modalities for the spine had a significant impact on the radiation doses given to this patient population. The CED for all the examination types of the spine considered was 5.4 manSv in 1979, increasing to 10.1 manSv in 1993, finally reaching 3.2 manSv in 2003. In spite of an increase in the total number of investigations, there was a decrease in the annual CED following the introduction of the MRI. The radiation dose per examination, regardless of modality, was reduced from 0.0017 manSv in 1979 to 0.00006 manSv in 2003.

6.3 Paper III

The total score for radiation knowledge among all respondents was a mean 30.4 or 42.8% of the maximum. Analyzed with a multiple linear regression analysis, the total score did not correlate with age, but differed between men and women (mean 31.4 vs. 28.2, $p=0.01$) and among the three main respondent groups ($p=0.03$).

Most respondents underestimated radiation doses from high dose imaging, while for thoracic spine and pelvic radiography, similar proportions of the respondents underestimated and overestimated the dose. According to 10.5% and 4.8% of respondents, MRI and ultrasound, respectively, implied some radiation dose. Awareness of referral guidelines was reported by 58.0% and 35.7% had used such guidelines.

It was found that 88.3% of the general practitioners, 83.1% of the hospital physicians and 56.9% of the non-physicians referred patients for imaging that would be most unlikely to affect treatment. General practitioners reported a higher percentage of such referrals (median 10%) than did hospital physicians (5%) and non-physicians (5%).

Compared with four other listed reasons for referrals that hardly affected treatment, “normal findings will reassure the patient” and to “give the patient the feeling of being taken seriously” were rated as more important. “Patient expectations” was rated as more important by general practitioners than by hospital physicians and non-physicians. Non-physicians rated “lack of time”, “expectations of relatives” and “to compensate for insufficient clinical

examination” as less important reasons than general practitioners and hospital physicians.

Lower weighting of radiation dose was related to admitting more referrals unlikely to affect treatment and not having used guidelines. However, the total radiation knowledge score was similar for clinicians denying and admitting referrals unlikely to affect treatment. Moreover, radiation knowledge did not correlate with their rate of such referrals, and was similar for those who had and those who had not used guidelines.

6.4 Paper IV

Comparing unfiltered low dose images and low dose 2D-filtered images with low dose 3D-filtered images, the low dose 3D-filtered images were rated as significantly superior for all image quality criteria. Normal dose images were rated as significantly superior to low dose 3D-filtered images for all image quality criteria, except for image noise. In a stratified analysis according to patient size ($BMI \leq 30 \text{ kg/m}^2$ or $> 30 \text{ kg/m}^2$), comparing 3D-filtered low dose images to normal dose images for small patients, delineation of the common bile duct (criterion 3) and image noise (criterion 4) were rated as significantly superior for the 3D-filtered images, while there was no significant difference for the other three image criteria. Hence, for patients with a $BMI \leq 30 \text{ kg/m}^2$, the 3D filter managed to restore low dose images to the quality of full dose images (Table 3).

Image quality criterion	Normal dose	Low dose unfiltered	Low dose 2D-filtered	Early phase
1: Delineation of pancreas	0.485°	-3.411***	-0.016°	-0.042°
2: Delineation of veins in liver	0.327°	-3.678***	-0.720**	0.832***
3: Delineation of the common bile duct	-0.574*	-3.235***	-0.626*	0.111°
4: Image noise	-1.297***	-7.022***	-1.495***	0.654**
5: Overall diagnostic acceptability	-0.000°	-4.263***	-0.768**	0.486*

Table 3. Results of Visual Grading Regression, stratified analysis, patient $BMI \leq 30 \text{ kg/m}^2$. Parameter values from ordinal logistic regression with significance levels. Positive values denote increased probability of higher scoring values compared to the 3D-filtered low-dose images (for the first three columns) or compared to the late phase (for the last column).

7. Discussion

7.1 Modality shifts

7.1.1 Paper I and II

From 1979 until the present, the way of recording the annual number of examinations in our department has changed as radiological information systems have been introduced and general organ system examinations have been replaced by more specific enhanced and non-enhanced examinations of certain organs. This introduces some uncertainties when comparing annual activity over such a long period of time. For instance, in our activity data, there seems to be an activity reduction from 1997 to 1998 for all modalities. However, this registered change is most probably an artifact due to changes in activity registration methods, and such methodological issue hardly affects the trends we are describing in papers I and II.

Concerning our dose estimates, the dose figures related to specific examination types in papers I and II are mean values of several Norwegian hospitals, since we did not have these figures available locally. Hence, the numbers used in papers I and II may not be totally representative of doses given at Drammen Hospital. However, the fact that the amount of radiation is reduced remains unchallenged by this uncertainty in absolute dose estimates. The results will be applicable to other hospitals as an illustration of the effects of modality shifts and a radiation protection policy.

In our studies of modality shifts, we wanted to explore how the introduction of non-x-ray-based modalities, together with the utilization of a radiation protection policy, would influence patient radiation doses. The radiation protection policy in the Radiological Department at Drammen Hospital was never formalized, but it has been an explicit goal to choose non-radiation based modalities whenever practical. To what extent our findings are due to technological developments alone or are also due to our radiation protection policy, we cannot establish from our results. To explore these issues independently, a study of two comparable institutions with different radiation protection policies and introducing new technology simultaneously would be necessary.

During the years 1979 to 2003, imaging was also performed at a private radiological institute in Drammen, offering mostly the same modalities as Drammen Hospital. We do not know if the reduction in x-ray-based

examinations seen at our hospital was compensated by an increase in such examinations at this private institute. If such compensation has occurred, the dose reduction to the patient population in the Drammen region as a whole - including the patient population of the private institute - may differ from that shown in our publications.

7.1.2 Supplementary study: modality shifts when imaging the gastrointestinal tract.

In a study not included in the thesis, we also looked at the shifts in imaging modalities of the gastrointestinal tract from 1979 to 2003, and its impact on patient radiation doses (162). There was a decrease in the total number of x-ray-based examinations to the gastrointestinal tract from 4,709 in 1979 to 2,199 in 2003. Per oral cholecystography / intravenous biligraphy were performed 376 times in 1979 and for the last time in 1993. From 1979 to 2003, x-ray-based esophagus examinations were reduced from 367 to 164, barium meals from 1,602 to 90, and barium enemas from 1,103 to 349. Small bowel barium increased from 143 to 232 and abdominal flat film increased from 973 to 1201. Endoscopic retrograde cholepancreaticography (ERCP) started in 1985 with 38 examinations and was performed 163 times in 2003 (Figure 11).

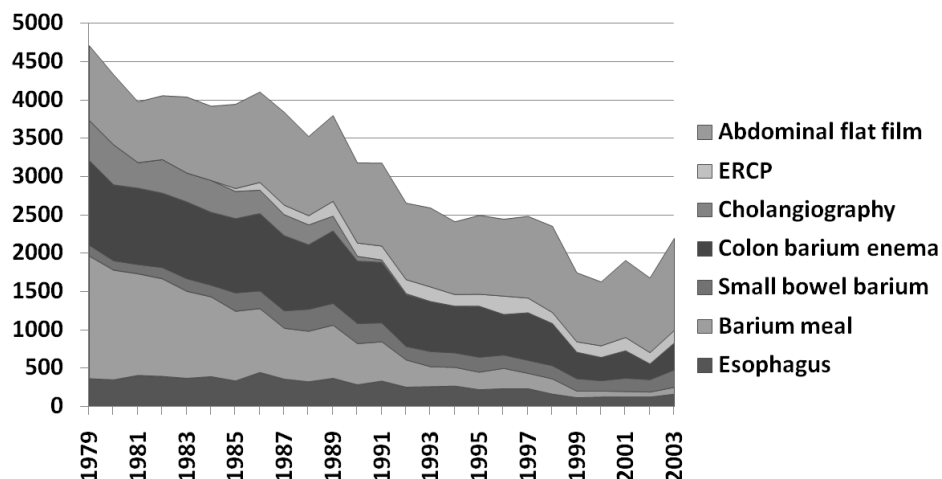


Figure 11. Number of x-ray-based examinations of the gastrointestinal tract at Drammen Hospital from 1979-2003.

The non-x-ray-based modalities of US, endoscopies and magnetic resonance cholepancreaticography (MRCP) increased from 516 examinations in 1979 to 4,067 in 2003. Gastroscopies increased from 516 to 2,037, colonoscopies started in 1980 with 27 examinations and increased to 896 in 2003. US increased from 11 examinations in 1983 to 805 in 2003. MRCP was introduced in 1998 with 71 examinations, and increased to 329 in 2003 (Figure 12).

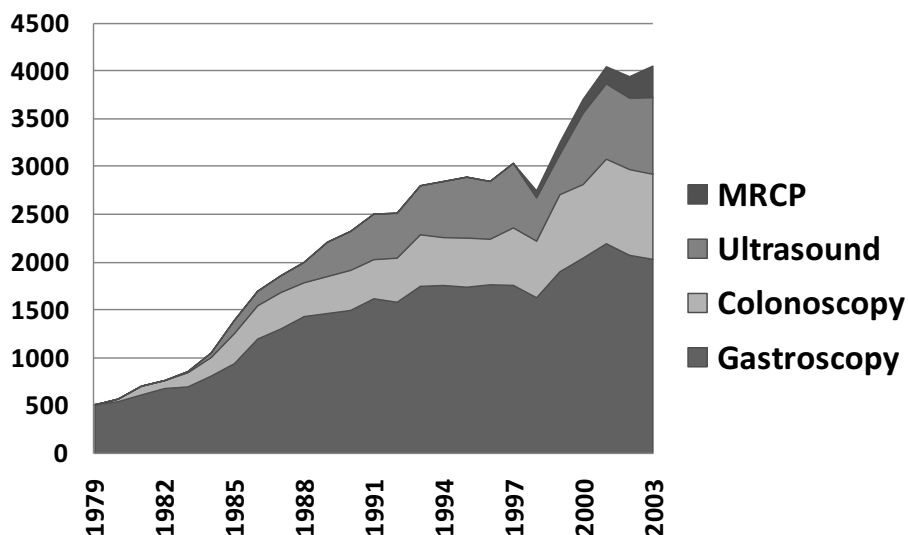


Figure 12. Number of non-x-ray-based examinations of the gastrointestinal tract at Drammen Hospital from 1979-2003.

The shift in modalities from 1979 to 2003 had a significant impact on the radiation doses given to this patient population. In spite of an increase in the total number of investigations from 5,225 examinations to 6,266, there was a reduction in radiation doses. The CED given was 22.0 manSv in 1979 and increased to 23.3 manSv in 1986. Thereafter, the CED substantially decreased to 10.1 manSv in 2003 (54.1% over the whole period) (Figure 13.)

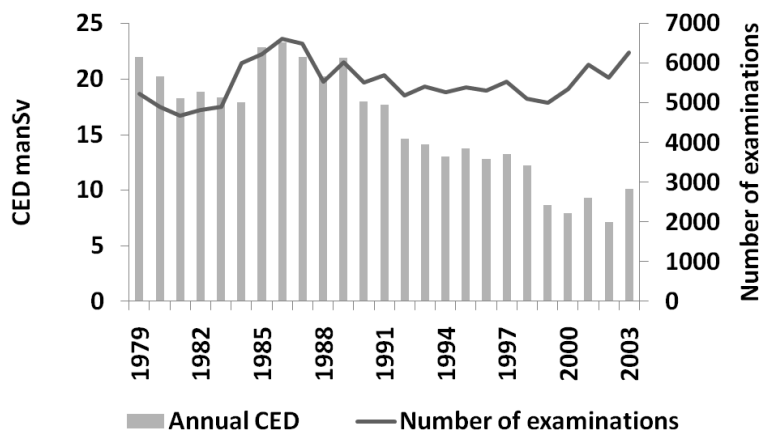


Figure 13. Radiation doses and total number of examinations of the gastrointestinal tract at Drammen Hospital from 1979-2003.

Theoretically, by using the risk coefficient for fatal cancer of 5% per Sv given by the ICRP(73), a reduction in CED shown in papers I, II and in the gastrointestinal study, would yield a reduction of about 90, 50 and 100 cases of radiation-induced fatal cancers per million examinations of the urinary tract, spine and gastrointestinal tract respectively. Looking more specifically at Norwegian conditions and spine examinations, the decrease in collective effective dose from examinations of the spine at Drammen Hospital from 1993 to 2003 was of the order of 65%. In 1993, 316,000 conventional x-ray and 38,000 CT examinations of the spine were performed (161). The total collective effective dose from spine examinations to the population (of 4.5 million people) was estimated at 515manSv. With the same policy and modality shift seen at Drammen Hospital, applied to all Norwegian hospitals, a reduction in CED of about 350 manSv would have been expected from 1993 to 2003 for the whole country. This would theoretically result in a reduction of 17 in the annual number of radiation-induced fatal cancers. From this perspective, it is obvious that the consequences of changing modalities in diagnostic imaging would have a major impact on public health.

Even though such estimates should be used carefully, they are useful when comparing different types of public radiation exposure. They are also useful when evaluating the cost benefit of different efforts to reduce the collective radiation detriment. For instance, the estimated reduction in radiation doses and radiation-induced fatal cancer incidents in papers I and II can be compared

to the estimated effect of introducing the 3D post-processing filter described in paper IV. In 2008, 169,158 abdominal CT scans with an average effective dose of 10 mSv were performed in Norway (13), resulting in a collective dose of around 1700 manSv. Lowering the effective dose by 40-50% from abdominal CTs would theoretically reduce the number of radiation-induced cancers resulting from this type of examination by 40 per year.

Dose and risk estimates in articles I and II are based on a hypothetical average patient, not taking into account the effect of age, sex and life expectancy at exposure. From a practical radiation protection point of view, it may be more relevant to look at certain patient groups and ultimately at the accumulated dose of the individual patient (163;164) when considering radiation doses and cancer risk estimates. Cancer patients receive the largest radiation doses, going through repeated examinations through primary diagnostics and frequent treatment response controls. However, a major proportion of these patients have a shortened life expectancy, and the stochastic effects of radiation may not be relevant for a large group of cancer patients (165;166). On the other side, patients with benign conditions such as pancreatitis (167), cystic fibrosis (168) and Crohn's disease (169) may also undergo repeated CT controls, and this exposure may be of more concern than that of many cancer patients. Regarding screening healthy patients with CT colonography or chest CT, the possible stochastic effects need to be taken even more carefully into account. When imaging children, with their increased radiation sensitivity and long life expectancy, radiation protection is of vital importance.

7.1.3 Recent trends and modality shifts at Drammen Hospital

During the years following our activity registrations described in papers I and II, from 2003 until the present, new imaging protocols have been developed for the modalities of US, MRI and MSCT, resulting in further modality shifts. From a radiation protection perspective, it would be favorable to continue the trend shown in papers I and II, replacing x-ray-based modalities with MRI or US. Examples of such further changes in our department during the last decade are the use of small bowel MRI and capsule endoscopy instead of small bowel barium (170), MRI replacing conventional digital subtraction angiography, US replacing phlebography for deep venous thrombosis in the calf (171), and contrast enhanced ultrasound instead of MSCT when screening for gastrointestinal cancer liver metastases in young patients (172). In contrast, and much more predominantly, a variety of new MSCT examination protocols have emerged, and in our department one single slice CT was replaced by two MSCT in 1993. As seen in Figure 14, the total number of CT examinations at our hospital doubled from 4,700 CT

examinations in 2002 to 11,335 in 2010, an increase affecting the organ systems of the spine, urinary and gastrointestinal tract.

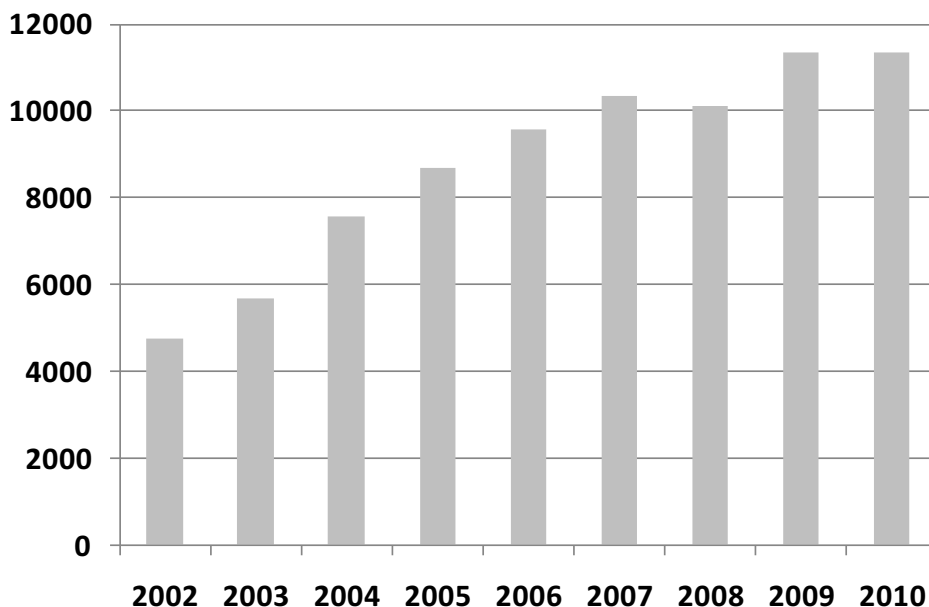


Figure 14. Total annual number of MSCT examinations performed at Drammen Hospital from 2002-2010.

The total number of MSCT examinations of the urinary tract was 65 in 2003 rising to 1,140 in 2010 (265 multi-contrast phase and 875 low dose calculus examinations). The number of IVPs decreased from 726 in 2003 to 8 in 2010, while plain radiographs of this organ system decreased from 323 to 127. US as well as MRI of this organ system remained practically unchanged.

From 2003 to 2010, the annual number of MSCT examinations of the cervical spine increased from 59 to 225, for the lumbar spine there was an increase from 35 to 164 examinations, while examinations of the thoracic spine remained about the same. During the same time period there was a decrease in the annual number of MRI spine examinations, from 2,483 examinations in 2003 to 2,288 in 2011, as well as the number of conventional spine x-ray examinations, which decreased from 2,697 to 2,398.

Colon barium was performed 349 times in 2003 and only 31 times in 2010, while colonoscopies increased from 896 examinations in 2003 to 1,217 in 2010. CT colonography was introduced in our department in 2005 and

increased from 35 to 254 annual examinations from 2005 to 2010. CT colonography seems have been introduced alongside colonoscopies, rather than replacing them (Figure 15). Barium meals and gastroscopies remained practically unchanged from 2003 to 2010. The total annual number of general abdominal CT examinations increased in the same time period from 590 to 1515.

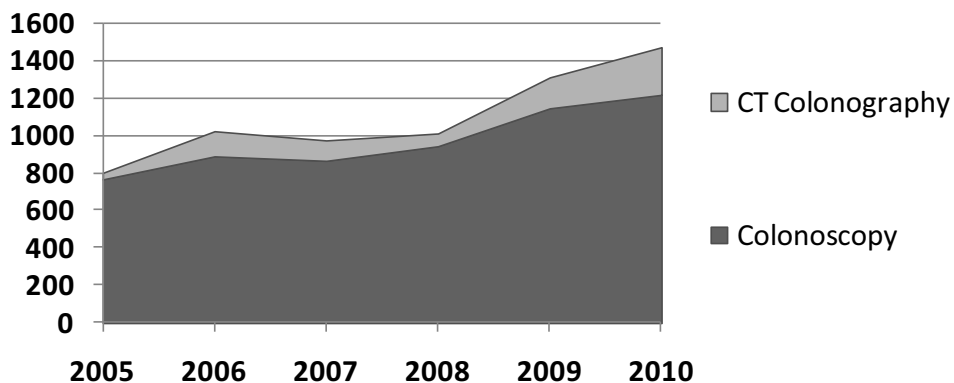


Figure 15. Annual number of colon examinations at Drammen Hospital during the years of 2005-2010.

We have not estimated the changes in radiation doses due to the introduction of MSCT at Drammen Hospital, but there has undoubtedly been a significant increase. This general trend in the increased use of MSCT and the concomitant increase in radiation doses has been described by several other authors (75;86).

To what degree the non-x-ray-based modalities will be able to replace MSCT or limit its growth in the future, we do not know. Whether US will be able to replace MSCT for indications other than those seen today depends on the inherent limitations of ultrasound as a modality, but also on the local ultrasound competence among the performing radiologists. Concerning MRI replacing MSCT, the considerably longer acquisition times for MRI with problems related to motion artifacts and critically ill patients, make MRI less robust and suitable for many indications. Other inherent modality differences, such as MSCT being better for evaluating calcifications and skeletal pathology, while MRI is superior for soft tissue, also limit to what degree MRI can replace MSCT. However, all modalities are being continuously developed, and focusing on radiation protection may inspire vendors to develop technology and protocols enabling a shift towards non-x-ray-based

modalities in the future. Besides these technical issues, the extent to which MRI can replace CT is also a question of resource allocation and health spending, given that MRI is a considerably more time consuming and hence more expensive type of examination.

In February 2011, a report was released by the Access to Medical Imaging Coalition in the United States, indicating that the era of rapid growth in medical imaging may have come to an end. The volume of advanced imaging services decreased by 0.1% from 2008-2009 (173).

7.2 Justification

7.2.1 Paper III

In our study addressing justification issues, a 100% participation rate and the unprepared, unaided responses to our questionnaire yielded more valid data on radiation knowledge than achievable in a postal or e-mail survey. However, the use of questionnaires has inherent limitations, as some answers reflect respondents' subjective opinions. In the present study, respondents' self report on their own practice should be interpreted with care; e.g. it may be biased by a wish to answer "correctly".

Not all questionnaires were returned with complete answers. Some questions were not answered, some respondents had rated answer alternatives independently rather than ranking them, and some respondents had obviously reversed the rating scales. When justified, these questionnaire answers were interpreted in co-author consensus and incorporated in the study material.

In our study all clinicians demonstrated limited radiation knowledge, and this concurs with other publications (174). This low knowledge level indicates a need for an increased focus on radiation protection issues in medical school. Currently in Norway, there are no national standards or guidelines for medical school curricula, concerning the content on radiation protection issues. Such requirements and recommendations have been developed by the EC (152;153), and corresponding regulations in Norway could probably help to raise radiation knowledge among Norwegian clinicians.

Besides underestimating the radiation dose from radiation intensive imaging procedures such as abdominal and chest MSCT, clinicians also often overestimated doses, and some even reported radiation from MRI and US, as has also been found in other studies (42;45;51-53;175). Thus, balanced information on radiation doses and risk estimates seems mandatory, avoiding underuse of MSCT when such examinations are indicated and justified (176).

Besides knowing the radiation dose due to a certain examination, prior patient radiation exposure is of importance when judging whether an x-ray-based imaging procedure is indicated. The total accumulated dose of a young, chronically ill patient can contraindicate further CT examinations if there are alternative modalities available. According to Norwegian law, radiation doses from radiation intensive imaging procedures must be recorded. However, accumulated individual radiation doses from CT examinations at Drammen Hospital are currently not available for the referring clinicians. To be able to track individual patient exposure, the IAEA has initiated the SmartCard project (177) and The Imaging Wisely campaign has launched a Patient Medical Imaging Record (178). With better integration of digital clinical record systems and radiological information systems, individual accumulated doses with corresponding risk estimates will hopefully become accessible for clinicians when considering referring patients for imaging procedures. Among physicians, referral guidelines were used to a limited extent; only 20% had used them, and the Norwegian translation of the EC guidelines was hardly known at all. The Norwegian translation, which has only been available on the web, has not been updated since 2003, and the marketing of the guidelines has been poor. Moreover, the structure of the guidelines might not be considered practical for use in daily clinical practice. Due to the lack of updating, the Norwegian translation was removed from the web in 2010. Referral guidelines need to be actively distributed and implemented (179-181), and should be incorporated into computerized referral systems, giving real-time, easily accessible decision support for referring clinicians (179;180;182;183).

In our study, referral practice and use of referral guidelines were correlated to weighting of radiation issues, but not to detailed radiation knowledge. Hence interventions to improve referral practice should target clinicians' attitudes, not just their detailed radiation knowledge. For many clinicians, being updated on the increasing complexity of medical imaging and relevant radiation doses is a demanding, if not impossible task. Examples of interventions that address attitudes as well as increase radiation knowledge are the Image Gently campaign (103) and the Image Wisely campaign (178).

7.2.2 Supplementary study: radiation knowledge and perception of referral practice among radiologists and radiographers

The fact that referring clinicians lack radiation knowledge and use referral guidelines only to a limited extent makes the role of the radiologist as a gate keeper in the justification process even more important. The need to strengthen the justification process has been recognized by Norwegian authorities and is

reflected in the recently ratified new Regulations (157) on the Law of Radiation Protection (156). The regulations now state that radiation-based imaging, nuclear imaging and MRI should only be performed when a patient is referred from a clinician possessing a referral license (ruling out self-referral), that referrals need to be justified by a relevant specialist, and that justification must be carried out according to current medical guidelines.

The assessment of referrals by the radiologists is done on the basis of clinical, radiological and radiation knowledge. When some of this information is lacking, the referring guidelines could also be of value for the radiologist. These considerations partially apply for radiographers, who perform imaging based on referrals that are not always checked by a radiologist. On this background, we explored the radiation knowledge and use of guidelines among radiologists and radiographers. The questionnaire from article III was handed out to unprepared radiologists (n=46, mean age 43.8 years) and radiographers (n=36, mean age 39.7 years). For exploring the radiation knowledge, the questions and analysis were identical to those in article III.

Radiologists and radiographers possessed significantly better radiation knowledge than clinicians ($p<0.001$, multiple linear regression analysis), the maximum score being 71p (Table4). Better knowledge hopefully makes them better able to evaluate the justification of an examination, compared to referring clinicians. However, the potential for improving radiation knowledge is there for all respondent groups. This complies with Lee et al (47), who found that radiation knowledge was limited among referring clinicians as well as among radiologists.

	Mean	N	Std. Deviation
Radiologists	41.1	46	9.2
Radiographers	38.2	36	7.6
Referring Clinicians	30.4	213	8.4

Table 4. Total score for radiation knowledge among radiologists, radiographers and referring clinicians.

More radiologists than radiographers and referring clinicians knew of and had used referral guidelines (Table 5). However, only 34.8% of the radiologists, 8.3% of the radiographers and 2.7% of the referring clinicians were able to state the website of the Norwegian translation of the EC referral guidelines.

	Knowledge of referral guidelines	Had used referral guidelines
Radiologists	39/46 (84.8%)	21/46 (45.7%)
Radiographers	14/36 (38.9%)	4/36 (11.1%)
Referring clinicians	123/212 (58.0%)	76/213 (35.7%)

Table 5. Knowledge and use of referral guidelines among radiologists, radiographers and referring clinicians.

When exploring to what degree imaging is unjustified, and designing efforts to improve the justification process, a relevant question would be if clinicians on one side, and radiologists and radiographers on the other side, have the same perception of today's referral practice. To what extent is today's practice considered justified on "each side of the table", and are radiation doses weighted equally? The questions exploring these issues in the questionnaire used in paper III were slightly rephrased for radiologists and radiographers, and handed out to the same respondents as mentioned above. For instance, clinicians were asked "What are your reasons for referring when imaging is unlikely to affect treatment", while radiologists and radiographers were asked "Why do you think patients are referred to your department for imaging, when imaging will probably not affect treatment".

Radiographers weighted radiation dose as more important than radiologists ($p=0.019$, Mann-Whitney test) and clinicians ($p=0.015$, Mann-Whitney test) (Figure 16), which may be explained by the fact that radiographers in their education and daily work are more closely engaged in the physical and radiation-related aspects of radiology. Clinicians rated radiation as insignificantly more important as radiologists did.

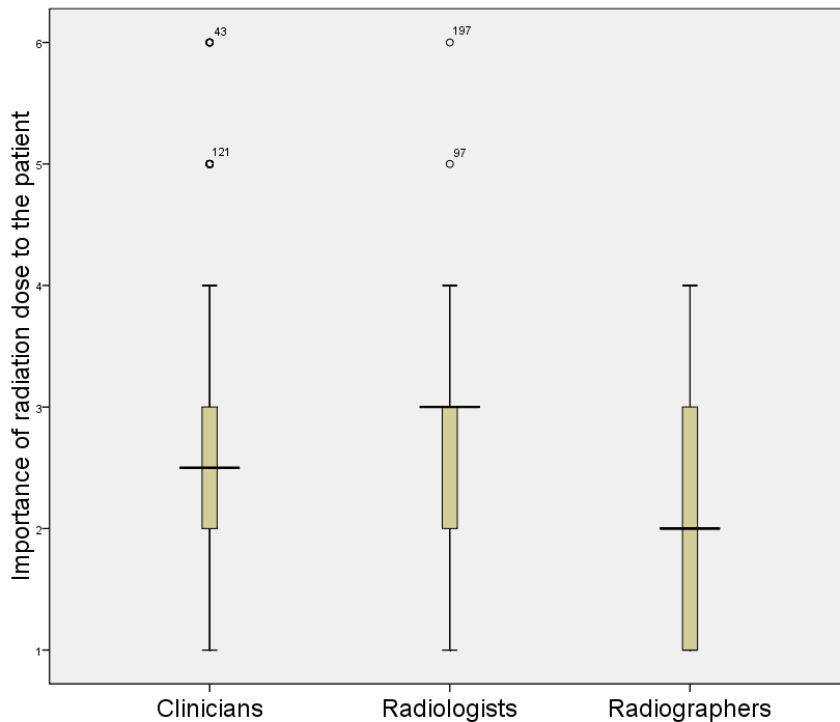


Figure 16. Weighting the importance of radiation dose in relation to referrals. 1=very important, 6=not important. Box-and-whisker plot where the box represents the interquartile range, the middle horizontal line the median and the whiskers the range. Numbered points are outliers.

It was found that 93.5% of radiologists and 91.7% of radiographers stated that they received referrals to imaging most unlikely to affect treatment, while 85.8% of referral clinicians admitted such referrals in their own practice. Radiographers perceived the highest proportion of such referrals (median of 20%), radiologists estimated the proportion to be 10% and clinicians 5%.

When rating reasons for referrals that were most unlikely to affect treatment (Table 6), “lack of time/getting the patient discharged” was rated as more important by radiologists compared to radiographers ($p=0.009$) and referring clinicians ($p=0.02$). “To compensate for limited clinical examination” was rated as more important by radiologists and radiographers (both $p<0.001$), compared to referring clinicians. Expectations of patients were rated as more important by radiologists than radiographers ($p=0.009$) and referring clinicians ($p=0.02$). P values calculated with Mann-Whitney test.

	Patient expectations	Give the patient the feeling of being taken seriously	Lack of time, "get the patient out of the office", discharge the patient	Expectations of relatives	Compensate for insufficient clinical examination	Normal findings will reassure the patient
Clinicians	3.0 (1.0)	2.0 (1.0)	4.0 (1.0)	3.0 (1.0)	4.0 (1.0)	2.0 (2.0)
Radiologists	2.0 (2.0)	2.0 (1.0)	2.0 (2.0)	3.0 (1.0)	2.0 (2.0)	2.0 (2.0)
Radiographers	1.0 (1.0)	1.0 (1.0)	3.0 (2.0)	2.0 (2.0)	2.0 (2.0)	2.0 (2.0)

Table 6. Median score (interquartile range) of reasons why clinicians refer patients for imaging that will probably not affect treatment, and score for what radiologists and radiographers consider the most important reasons for patients being referred to such examinations. 1=very important, 4=not important.

These findings indicate that radiologists and radiographers differ from clinicians in the perception of the extent to which patients are referred for imaging that is most unlikely to affect treatment, and of the reasons for such referrals. There may be several causes for this discrepancy. The digitalization of radiology has increased the distance between the referral clinicians, radiologists and radiographers. Electronic referrals and reports, together with decentralized instant image access have partially eliminated the need for physical meetings. The increasing volume of imaging procedures has put radiologists under pressure, marginalizing consultations between radiologists and clinicians. Inadequate referrals (184-186) and failing to communicate sufficient information may also explain some of the perception differences.

Besides reinforcing radiation knowledge and the use of referral guidelines among referring clinicians as well as radiologists and radiographers, there seems to be a need for efforts to improve the communication between radiologists, radiographers and referring clinicians. This would hopefully help to preserve, or perhaps reestablish, a common understanding of radiation issues, justification, and today's referring practice.

Looking at justification in an even wider perspective, the impact of radiology on the actual medical outcome (187) for the patient and the society as a whole should be evaluated. On the other hand, we need to establish certain knowledge of the detrimental effects of ionizing radiation in the dose ranges of medical imaging. Only when this knowledge is established can we truly evaluate the health benefits of radiology against the costs of detrimental radiation effects, and be in a position to decide whether an imaging procedure

is truly justified or not.

7.3 Optimization – paper IV

In paper IV, addressing radiation optimization, image quality is based on the evaluation of normal anatomical structures. The true clinical value of images, however, lies in their sensitivity and specificity for pathology. Such matters could be explored through an ROC study (141;142), which would be a more complex and costly study. The practical difficulties of ROC studies make complementary ways of evaluating image quality indispensable, and we believe that the evaluation of normal anatomy in filtered images yields valid information about the clinical value of images (143).

With few exceptions (125;130), earlier publications on filter effects on abdominal CT have been based on evaluating images in a randomized but not pair wise manner (118;122;127;129;188). We believe that a relative and simultaneous comparison of two image series rather than an absolute evaluation of one image series at a time, is a more sensitive method for detecting subtle image quality differences. Our way of scoring two image series simultaneously should also be less dependent on the inter-individual variation among the readers on what constitutes acceptable image quality, as well as on the intra-individual variation within every reader, knowing that the threshold for what to consider acceptable may change through the scoring process of such an image quality evaluation.

The images were evaluated by readers who were not involved in the study, apart from doing the actual image scoring. For an observer working with different image reconstructing and post-processing methods, the texture of the images may reveal what technique has been used. This fact may bias presumably blinded studies if readers familiar with the different techniques take part in the whole study process. Also, none of the readers were co-authors of this publication; hence they should not have had preferences when scoring filter performance, thus reducing publication bias.

Prior to the study, the mean mAs of standard clinical abdominal scans in our department were known to be somewhat higher than 180 mAs. Since the protocol was considered not fully optimized, 180 mAs was chosen as the full dose level in our study. This might imply that the readers were exposed to study images that were somewhat inferior to images in the daily routine. However, doing a side by side and relative comparison of the images series, we believe that our chosen normal dose level yields valid scoring results. Mean

mAs and CDTI_{vol} of the standard clinical scans for our 12 study patients were 244mAs and 16.3 mGy respectively.

The fixed mAs in the full dose and low dose images (as opposed to using automatic exposure control or manually setting the tube current according to patient size) was chosen in order to fully control acquisition parameters, as well as to be able to explore how patient size and baseline image quality affected the 2D and 3D filter performance. The dose reduction level of 50% was chosen on the basis of pilot testing of the filters and prior publications on 2D post-processing filters, as well as 3D raw data and algorithm filters (123;124;138).

Abdominal CT is a radiation intensive and frequently performed examination. In 2008, by far the largest contributor to the total CED in Norway was abdominal CT (13). In a study including about 1 million patients, Fazel et al found abdominal CT to be the second largest CED contributor, next to myocardial perfusion imaging (86). Thus, a 40-50% dose reduction by a 3D post-processing filter would provide an effective optimizing tool with a great impact on the total patient radiation exposure.

Besides lowering the radiation doses, post-processed images may help speed up and ease the radiological workflow. When interpreting images, the human eye is able to extract information from a noisy background, which in many ways is similar to how post-processing filters lower noise and enhances structures. However, extracting information from noisy images by the human eye takes time and is energy consuming. Thus, a post-processing filter may ease the work of radiologists, and allow them to read more images at a higher pace.

A recently introduced optimizing tool is iterative reconstruction, which allows a considerable dose reduction (138;189). One might argue that post-processing filters are superfluous in the era of iterative reconstruction, but this latest optimizing technology might probably not be applicable for older 4-16 slice scanners, which will still be the workhorses in many radiological departments in the years to come. Thus, we believe post-processing filter technology will be a relevant optimizing tool also in the future.

Whether 3D filters will become an important optimizing tool in the future depends on what the restoration capacity of a fully developed filter will be, and to what degree iterative reconstruction and other optimizing tools make post-processing filters superfluous. However, besides developing new optimizing tools, much of the challenge in CT optimization today is to utilize available tools and translate current knowledge into daily practice. For abdominal and

cerebral CT in Norway, variations with a factor of 3-4 in local diagnostic reference levels were found in a study by Silkoset (190). The study also revealed that departments with postgraduate CT-educated radiographers and a multidisciplinary radiation protection team, revising their protocols frequently, had CT protocols with lower radiation doses. Large variations were seen between institutions having identical scanners. These findings support the assumption that much optimizing work remains to be done on the basis of current tools and technical possibilities.

7. Conclusions

Some major conclusions from the present thesis may be summarized as follows:

- When imaging the urinary tract, the spine and the gastrointestinal tract in the years 1979-2003, the introduction of US, MRI and endoscopies, together with a radiation protective policy, reduced the ionizing radiation doses given to these patient populations, in spite of an increase in the total number of examinations of these organ systems.
- Referring clinicians demonstrated limited radiation knowledge. Scanty radiation knowledge and limited use of referral guidelines indicate that the process of justifying imaging referrals needs to be improved. We found support for the hypothesis that clinicians who put less weight radiation issues a) more often refer to imaging unlikely to affect treatment, and b) to a less extent use referral guidelines. Detailed radiation knowledge was not correlated to referral practice.
- Radiologists and radiographers possess somewhat better radiation knowledge than referring clinicians. Radiologists and radiographers differ from clinicians in their perception of the extent to which patients are referred for imaging unlikely to affect treatment, and on the reasons for such referrals.
- The quality of 3D filtered reduced dose abdominal CT images was superior compared to reduced dose unfiltered and 2D filtered images. For patients with BMI < 30 kg/m², 3D filtered images were comparable to standard dose images. A 3D post-processing filter is a powerful optimizing tool and allows for considerable dose reduction.

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9. Paper I-IV

Clinicians' justification of imaging: do radiation issues play a role?

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Abstract

Objective To explore clinicians' knowledge and consideration of radiation, in relation to their referral practice and use of referral guidelines for imaging.

Methods A questionnaire was handed out to 213 clinicians in Norway; all responded: 77 general practitioners, 71 hospital physicians and 65 non-physicians (55 manual physiotherapists, 10 chiropractors). Questions concerned weighting of radiation dose, guideline use, referrals unlikely to affect treatment, doses from imaging procedures, ranking of imaging as radiation source, and deterministic and stochastic effects. For radiation knowledge, a total score was aggregated.

Results The mean radiation knowledge score was 30.4/71. Most respondents underestimated doses from high-dose imaging, e.g., barium enema (94.7%), chest CT (57.7%) and abdominal CT (52.7%). Limited radiation knowledge was not compensated by using guidelines. Only 20% of physicians and 72% of non-physicians used referral guidelines. Non-physicians weighted radiation dose as being more important than physicians when referring; they also

reported fewer referrals as being unlikely to affect treatment. Such referrals and not using guidelines were related to lower weighting of radiation dose but not to radiation knowledge.

Conclusion Limited radiation knowledge and guideline use indicate suboptimal justification of referrals. When justifying imaging, weighting of radiation dose may play a larger role than detailed radiation knowledge.

Keywords Diagnostic imaging · Referral guidelines · Radiation dosage · Questionnaires · Radiation protection

Introduction

The increasing volume of medical imaging and particularly multislice computed tomography (CT) during the last few decades has turned radiation protection into one of the main concerns of the radiological community [1–4]. Justification and optimisation are cornerstones of radiation protection [5, 6], and this report deals with justification.

To be able to justify a radiation-based medical imaging procedure—that is, to weigh its costs against its benefits [6]—the referring clinician needs to know the magnitude of the radiation dose given and the possible detrimental effects of this exposure. To some degree, the lack of such knowledge could be compensated for by using referral guidelines [7–9] in the justification process.

Former studies have revealed that referring physicians possess limited knowledge about ionising radiation and its carcinogenic potential [10–22], and that referral guidelines are not widely used [23–26]. However, we have little data on radiation knowledge and use of referral guidelines among referring non-physicians, e.g., chiropractors [27, 28]. We also lack data on how knowledge and attitudes about radiation

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Table 1 Questions about medical radiation use and radiation protection

Questions	Response categories
To what extent are the listed factors important when you refer a patient for imaging? Radiation dose to patient Patient's wish Impact on diagnosis Impact on treatment Impact on patient's future health	Weighting of importance 1–6; 1 = very important, 6 = not important
Do you know of imaging referral guidelines where referrers can seek information on which investigations are indicated for which conditions?	Yes/no
Have you ever used such referral guidelines?	Yes/no
Do you refer patients for imaging in cases when you consider it most unlikely that the imaging results will affect treatment of the patient?	Yes/no
If yes, what is the proportion of such referrals among all your referrals (circa)?	1%, 5%, 10%, 20%, 50%
What are the reasons why you may refer when the imaging results most likely will not affect treatment? Please weight the listed reasons Patient expectations Give the patient the feeling of being taken seriously Lack of time, “get the patient out of the office”, discharge the patient Expectations from relatives Compensate for insufficient clinical examination Normal findings will reassure the patient	Weighting of importance 1–4; 1 = very important, 4 = not important
Please estimate the effective dose of the listed imaging procedures, compared to a chest x-ray (front and side projection). Please put a mark, even if you are uncertain ^a Cerebral CT Pelvic radiography Cerebral MRI Intravenous pyelography Chest CT Barium meal fluoroscopy Barium enema Abdominal CT Kidney ultrasound Thoracic spine radiography Sinus x-ray Sinus CT	Corresponding numbers of chest x-rays (front and side projection): 0–1, 1–10, 10–50, 50–200
We ask you to rank the contributors to the mean effective radiation dose for a Norwegian in 2006 Medical imaging Radon in homes Background gamma radiation Pollution from Sellafield in England Pollution from the Chernobyl nuclear plant accident	Rank, 1 = largest contributor, 5 = smallest contributor
Detrimental effects of radiation are divided into deterministic and stochastic effects. Are you familiar with these terms? If yes, go to next question	Yes/no

Table 1 (continued)

Questions	Response categories
This is a list of potential detrimental effects of radiation. Please mark whether you think these effects are stochastic or deterministic (one mark per effect) Leukaemia Infertility Foetus abnormalities Genetic adverse effects Cataract Lung cancer	Stochastic/deterministic

^a Estimates of effective dose were compared with national reference values or—when such values were lacking—with doses measured at the first author’s department

issues may relate to referral practice. Further data could help to design strategies for improving different clinicians’ justification processes and referral practices.

Accordingly, we explored general practitioners’, hospital physicians’ and non-physicians’ (1) radiation knowledge, (2) weighting of radiation dose when referring, (3) use of referral guidelines, (4) rate of and reasons for referrals unlikely to affect treatment, and (5) if this rate and their guideline use is related to their radiation knowledge and weighting. We hypothesised that clinicians who put less emphasis on radiation issues order imaging unlikely to affect treatment more often and use referral guidelines less often.

Materials and methods

In this study from Norway, hospital physicians, general practitioners, manual physiotherapists and chiropractors filled in an anonymous questionnaire. Manual physiotherapists acquired a referral licence for all techniques in 2006

and chiropractors in 1991 [29]. The study did not require approval from a research ethics committee.

Our questionnaire was based on literature review, a pilot study of six respondents and individual interviews with four clinicians to test face validity. It was handed out to 71 hospital physicians at all grades during their morning meetings at a 500-bed general hospital and to 77 general practitioners, 55 manual physiotherapists and 10 chiropractors during lectures at nation- or countywide courses of general interest within their fields, not related to radiation issues. All clinicians attending the actual meetings/ lectures were asked to fill in the questionnaire, which took about 15 min. They were not informed about the questionnaire session in advance. The first author supervised this session to ensure unaided answers.

The questions concerned, in this order: respondents’ age and gender, their weighting of (six-point scale) radiation dose and four other factors (Table 1) when referring for imaging, whether they knew of (yes/no) and had used (yes/no) referral guidelines, if they referred for imaging that most unlikely would affect treatment (yes/no), their approximate rate of such referrals (1, 5, 10, 20 or 50%) and the importance of (four-point scale) six listed reasons for such referrals (Table 1).

The next question was about effective dose, in number of chest x-rays (0–1, 1–10, 10–50 or 50–200) from 12 imaging procedures including radiography, fluoroscopy, CT, magnetic resonance imaging (MRI) and ultrasound [30] (Table 1). Respondents then had to rank the contribution of medical imaging to the mean effective dose for a Norwegian, compared with that of radon in homes, background gamma radiation, pollution from Sellafield in England and food pollution from the Chernobyl nuclear plant accident [31]. Finally, respondents were asked if they knew the terms deterministic and stochastic effects; if so, they should categorise six effects as either deterministic or stochastic [5].

We constructed a total radiation knowledge score ranging from 0 to 71. For the 12 imaging procedures, a

Table 2 Total radiation knowledge score by respondent group

	N	Mean score	SD
General practitioners	77	31.0	8.4
Hospital physicians	71	32.3	9.4
Surgeons	13	34.2	10.3
Internists	19	37.0	11.6
Neurologists	10	24.9	4.6
Orthopaedics	12	31.4	5.3
Paediatricians	13	30.9	8.4
Rheumatologists	4	29.5	5.2
Non-physicians	65	27.7	6.7
Manual physiotherapists	55	27.3	6.4
Chiropractors	10	30.3	8.4

Mean score was significantly different among general practitioners, hospital physicians and non-physicians: $p=0.03$, multiple linear regression analysis

correct dose gave 3 points and the closest wrong dose 1 point, yielding a maximum of 36 points. Ranking of radiation sources gave a maximum of 18 points. Ranking radon first and imaging second gave 9 points each, and the closest wrong rank gave 4 points. Knowing the terms stochastic and deterministic gave 5 points, and categorising the six detrimental effects correctly gave 2 points each, resulting in a maximum of 17 points. Missing data gave 0 points, and a total radiation knowledge score was noted for all participants.

For continuous normal distributed data, we used Student's t-test and for categorical data, Wilcoxon signed rank test, Kruskal-Wallis, Mann-Whitney, Friedman's and chi-squared tests, and Spearman's rho, as appropriate (see Results). Multiple linear regression analysis was used to examine factors that could influence radiation knowledge. Data were analysed using SPSS (version 16, SPSS Inc., Chicago, IL). A two-tailed $p < 0.05$ was accepted as statistically significant.

Results

All invited clinicians ($n=213$) participated in the study. Their mean age (range) was 44.6 (26–73) years. There was a male predominance (66%–75%) within all three main respondent groups (77 general practitioners, 71 hospital physicians and 65 non-physicians).

Radiation knowledge

The total score of radiation knowledge was mean 30.4 (SD 8.5) or 42.8% of the maximum. Analysed with a multiple linear regression analysis, total score did not correlate with age, but differed between men and women (mean 31.4 vs. 28.2, $p=0.01$) and among the three main respondent groups ($p=0.03$, Table 2). Age, sex and group explained only 6.4% of the variation in this score ($R^2=0.064$).

Most respondents underestimated radiation doses from high dose imaging: for barium enema 94.7%, barium meal 68.3%, chest CT 57.6%, intravenous pyelography 55.1% and abdominal CT 52.7% (Fig. 1a). The dose from paranasal sinus CT (Fig. 1b) was overestimated by 94.8%. For thoracic spine and pelvic radiography (Fig. 1c), similar proportions underestimated (21.6%, 18.7%) and overestimated dose (19.7%, 19.1%). According to 10.5% and 4.8% of respondents, MRI and ultrasound, respectively, implied some radiation dose. Dose estimates were given by 205–208 (96%–98%) of the 213 participants.

When ranking the magnitude of five different radiation sources for an average Norwegian, 38 (18.2%) out of 209 respondents correctly ranked medical imaging (1.1 mSv/year)

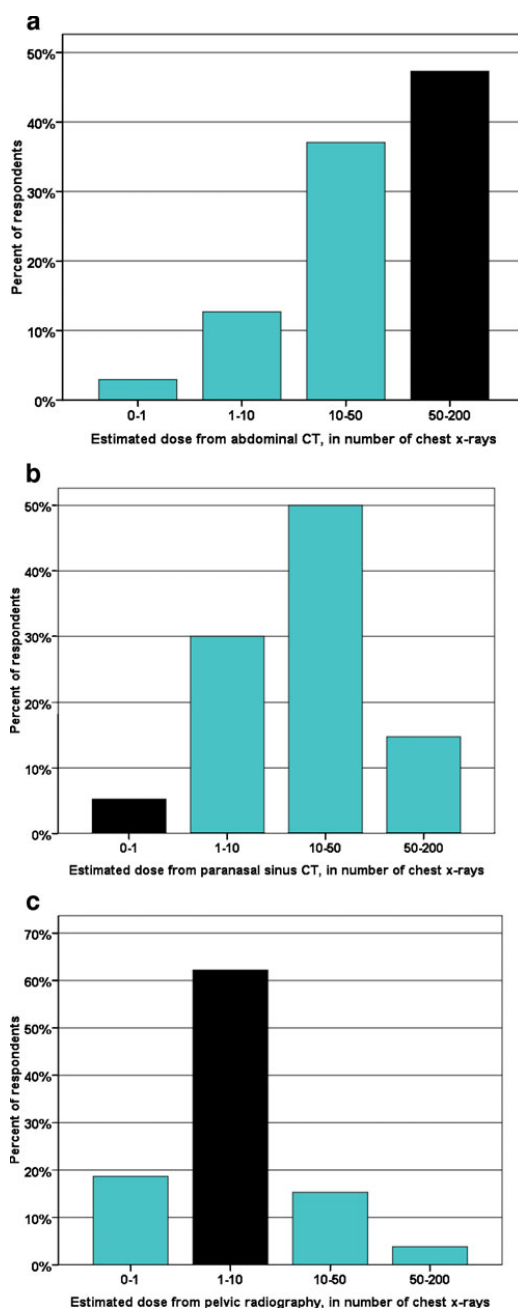


Fig. 1 Distribution of respondents according to their radiation dose estimates in number of chest x-rays for abdominal CT (**a**), paranasal sinus CT (**b**) and pelvic radiography (**c**). Correct answers are marked in black

Table 3 Median score (interquartile range) for weighting the importance of different factors when referring for imaging: 1 = very important, 6 = not important

	Radiation dose	Patient's wish	Impact of imaging on diagnosis	Impact of imaging on treatment	Impact of imaging on future health
General practitioners (n=77)	3.0 (2.0)	4.0 (3.0)	1.0 (1.0)	1.0 (0.0)	1.0 (1.0)
Hospital physicians (n=70)	3.0 (1.0)	4.0 (2.0)	1.0 (1.0)	1.0 (0.0)	1.0 (1.0)
Non-physicians (n=65)	2.0 (2.0)	5.0 (1.0)	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)
Total (n=212)	2.5 (1.0)	4.0 (2.0)	1.0 (1.0)	1.0 (0.0)	1.0 (1.0)

as second after radon (3.0 mSv/year); 72 (34.4%) ranked imaging too high and 99 (47.4%) too low.

Only 34 (16.7%) out of 204 respondents stated they knew the terms deterministic and stochastic effects. When categorising six different detrimental effects as either stochastic or deterministic, these 34 respondents' mean score was 6.8/12; chance would yield 6/12.

Weighting of radiation dose when referring

Considering a referral for imaging, respondents in the total sample weighted radiation dose as more important than the patient's wish ($p<0.001$, Wilcoxon signed rank test), but less important than the impact of the imaging on the patient's diagnosis, treatment or future health ($p<0.001$, Friedman's test) (Table 3). Non-physicians rated radiation dose as more important than did general practitioners ($p<0.001$, Mann-Whitney test) and hospital physicians ($p=0.001$, Mann-Whitney test). Complete ratings were given by 212 (99.5%) of the respondents.

Use of referral guidelines

Only 58.0% (123/212) reported that they knew of referral guidelines, and 35.7% (76/213) had made use of such guidelines. The proportion that had used guidelines was higher for non-physicians (72.3%) than for general practitioners (19.5%) and hospital physicians (19.7%) ($p<0.001$, chi-squared tests).

Referrals unlikely to affect treatment

As many as 88.3% of the general practitioners, 83.1% of the hospital physicians and 56.9% of the non-physicians referred for imaging that would be most unlikely to affect treatment ($p<0.001$, chi-squared test). General practitioners reported a higher percentage of such referrals (median 10%) than did hospital physicians (5%, $p=0.04$, chi-squared test) and non-physicians (5%, $p<0.001$, chi-squared test).

Compared with the other four listed reasons for referrals that hardly affect treatment (Table 1), "normal findings will reassure the patient" and to "give the patient the feeling of

being taken seriously" were rated as more important ($p<0.001$, Friedman's test). "Patient expectations" was rated as more important by general practitioners than by hospital physicians and non-physicians ($p<0.001$, Mann-Whitney test). Non-physicians rated "lack of time", "expectations from relatives" and to "compensate for insufficient clinical examination" as less important reasons than general practitioners and hospital physicians ($p<0.001$, Mann-Whitney test).

Radiation issues in relation to referrals and guideline use

Lower weighting of radiation dose was related to admitting referrals unlikely to affect treatment (Figs. 2 and 3) and not having used guidelines (Fig. 4). However, the total radiation knowledge score was similar for clinicians denying ($n=49$) and admitting ($n=164$) referrals unlikely to affect treatment (mean 28.7 vs. 31.0, $p=0.10$, Student's *t*-test), did not correlate with their rate of such referrals ($r=0.14$, $p=0.85$, Spearman rho), and was similar for those

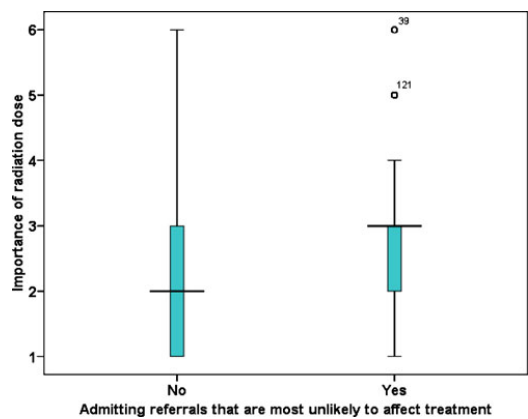


Fig. 2 Weighting the importance of radiation dose in relation to admitting referrals that are most unlikely to affect treatment ($r=0.14$, $p=0.037$, Spearman rho). 1 = very important, 6 = not important. Box-and-whisker plot where the grey box represents the interquartile range, the middle horizontal line the median and the whiskers the range. Numbered points are outliers

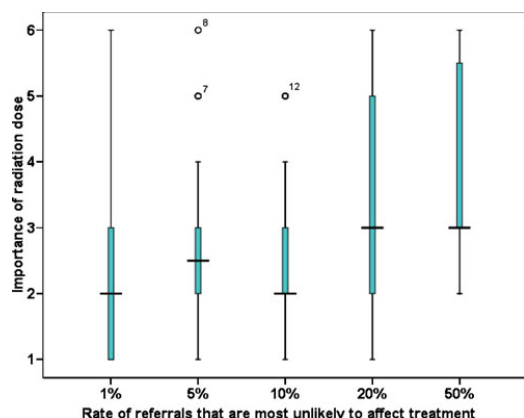


Fig. 3 Weighting the importance of radiation dose in relation to percentage of referrals being most unlikely to affect treatment ($r=0.21$, $p=0.005$, Spearman rho). 1 = very important, 6 = not important. Box-and-whisker plot where the grey box represents the interquartile range, the middle horizontal line the median and the whiskers the range. Numbered points are outliers

who had and those who had not used guidelines (mean 29.4 vs. 31.0, $p=0.18$, Student's t-test).

Discussion

In this study, all three respondent groups possessed limited radiation knowledge, and 80% of the physicians did not use referral guidelines. Respondents who weighted radiation dose lower when referring reported less guideline use and

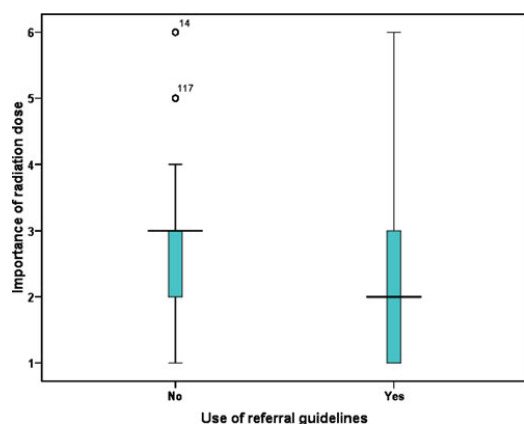


Fig. 4 Weighting the importance of radiation dose in relation to using referral guidelines ($r=0.18$, $p=0.009$, Spearman rho). 1 = very important, 6 = not important. Box-and-whisker plot where the grey box represents the interquartile range, the middle horizontal line the median and the whiskers the range. Numbered points are outliers

more referrals as being unlikely to affect treatment. Non-physicians reported fewer such referrals, more use of referral guidelines and more weight on radiation dose.

Strengths and limitations

A 100% participation rate and the unprepared, unaided responses to our questionnaire yielded more valid data on radiation knowledge than achievable in a postal or e-mail survey. However, the use of questionnaires has inherent limitations, as some answers reflect respondents' subjective opinions. In the present study, respondents' self report on their own practice should be interpreted with care, e.g., it may be biased by a wish to answer "correctly". Such bias was reduced by avoiding respondent identifiers on the questionnaire and hardly explains the most salient differences and relations.

Since responses had to be unprepared and supervised, it was not feasible to recruit respondents randomly from their respective professional groups to achieve a representative sample. Our respondents may nevertheless be fairly comparable to their groups on a national level. Mean age in the study sample vs. the national population was 48.1 vs. 46.8 years for general practitioners and 40.0 vs. 43.3 years for hospital physicians [32]. Hospital physicians were recruited at morning meetings for all residents, junior and senior physicians at a general hospital with common subspecialties (Table 2). General practitioners and non-physicians were recruited from courses of general interest.

Discussion of findings

Our study confirmed that clinicians often underestimate radiation doses [10–22]. However, clinicians overestimated doses too, and some even reported radiation from MRI and ultrasound, as has also been found in other studies [10–12, 17, 19, 22]. Similarly, physicians in a former study overestimated the teratogenic risk from ionising imaging [33]. Thus, balanced information on radiation doses and risks seems mandatory.

Despite their slightly poorer radiation knowledge, non-physicians put more weight on radiation dose when referring. One reason for this may be that non-physicians face mostly benign conditions, where radiation dose is more relevant than in cases of for example malignancy. A less likely reason, but one that we cannot rule out, is that some manual physiotherapists may have rated radiation dose higher to show that they deserve their recently acquired referral licence.

Although concurring with previous findings [24, 25, 34], it was remarkable that only 20% of the physicians had used referral guidelines. Clearly, few physicians used the

Norwegian translation of the EU Commission Guidelines available on the web [35]. The much higher proportion (72%) of non-physicians using guidelines could be partly explained by the fact that the manual physiotherapists have developed their own guidelines [36] and that sub-specialists may be more familiar with their own adapted guidelines than with general guidelines on the same topic [26]. More use of referral guidelines among manual physiotherapists may also be partly due to their relatively short experience with imaging referrals.

Respondents' rates of referrals unlikely to affect treatment were smaller than some reported rates of unjustified imaging (5–10% vs. 20%) [37–39]. Our respondents may have underestimated their own rates, but the rate of unjustified and/or treatment-irrelevant imaging in Norway is not known.

As limited radiation knowledge was not compensated for by using referral guidelines, relevant information may have lacked in the justification process. Our study was not designed to examine the effect of efforts to improve this process. Yet, a higher weighting of radiation dose when referring was related to more guideline use and fewer referrals regarded as being unlikely to affect treatment. We therefore believe that increased weighting of radiation dose can help to optimise referral practice.

Implications and conclusions

Our findings do not necessarily apply in other health care systems, and they need confirmation in further studies. Nonetheless, these results have implications that may be of value to those attempting to improve the justification of imaging in cooperation with clinicians.

First, referring clinicians, both non-physicians and physicians, need information about radiation protection and the detrimental effects of radiation. To prevent overuse as well as underuse of medical imaging, this information must be balanced.

Second, referral guidelines should be more actively distributed and implemented [40–42]. For example, as a start, one could incorporate such guidelines into every hospital's computerised referral system, giving real-time, easily accessible decision support for referring clinicians [24, 42–46].

Third, interventions to improve referral practice should target clinicians' attitudes and not only their knowledge. Clinicians' weighting of radiation dose seems more important to their referral practice than their detailed radiation knowledge.

Fourth, different interventions may be required for non-physicians and physicians, as they may differ in their attitudes towards radiation issues and in pre-existing guideline use and referral practice.

In conclusion, scarce radiation knowledge and limited use of referral guidelines indicate that the process of justifying imaging referrals needs to be improved. In this process, weighting of radiation dose played a larger role than detailed radiation knowledge. We found support for the hypothesis that clinicians who put less weight on radiation issues order imaging unlikely to affect treatment more often and use referral guidelines less often. Non-physicians used guidelines more often than physicians and weighted radiation dose as being more important. Efforts to improve the justification of radiation-based medical imaging should nevertheless raise awareness of radiation protection issues among all groups of referring clinicians.

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Application of adaptive nonlinear 2D and 3D post-processing filters for reduced dose abdominal CT

Abstract

Background: Abdominal computed tomography (CT) is a frequently performed imaging procedure, resulting in considerable radiation doses to the patient population. Post-processing filters are one of several dose reduction measures that might help to reduce radiation doses without loss of image quality.

Purpose: To assess and compare the effect of two and three-dimensional (2D, 3D) non-linear adaptive filters on reduced dose abdominal CT images.

Material and Methods: Two baseline abdominal CT image series with a volume computer tomography dose index (CTDI_{vol}) of 12 mGy and 6 mGy were acquired for 12 patients. Reduced dose images were post-processed with 2D and 3D filters. Six radiologists performed blinded randomized, side-by-side image quality assessments. Objective noise was measured. Data were analyzed using visual grading regression and mixed linear models.

Results: All image quality criteria were rated as superior for 3D filtered images compared to reduced dose baseline and 2D filtered images ($p < 0.01$). Standard dose images had better image quality than reduced dose 3D filtered images ($p < 0.01$), but similar image noise. For patients with body mass index (BMI) $< 30 \text{ kg/m}^2$ however, 3D filtered images were rated significantly better than normal dose images for two image criteria ($p < 0.05$), while no significant difference was found for the remaining three image criteria ($p > 0.05$). There were no significant variations of objective noise between standard dose and 2D or 3D filtered images.

Conclusions: The quality of 3D filtered reduced dose abdominal CT images is superior compared to reduced dose unfiltered and 2D filtered images. For patients with BMI < 30 kg/m², 3D filtered images are comparable to standard dose images.

Keywords:

Abdomen/GI, CT, Pancreas, Adults, Computer Applications, Radiation Safety

Concerns over a potential increase in the risk of radiation-induced carcinogenesis due to the increasing use of CT scanning have increased the interest of radiologists, medical imaging physicists and CT vendors in radiation dose reduction (1-3).

When examining organs or structures with low contrast lesions, such as the liver or pancreas, increased image noise in lower dose CT can adversely affect image quality and diagnostic confidence. Recently, some CT vendors have made available iterative reconstruction techniques to reduce noise in reduced dose CT images acquired on their higher end or latest equipment. Another way of reducing patient doses is through the application of image post-processing filters on lower dose CT, which reduces image noise to enable CT scanning with a lower dose without losing clinical information. Image post-processing filters can operate in an image plane (2D filters) or within a volume including the z-direction (3D filters). Prior studies have evaluated the use of 2D (4-6) or 3D (7,8) filters, but to the best of our knowledge, no direct comparisons of 2D and 3D filters for enabling radiation dose reduction have been published at the time of preparation of this manuscript. Therefore, the purpose of our study was to assess and compare the effects of 2D and 3D non-linear adaptive filters on reduced dose abdominal CT images.

Material and Methods

Patients

Our Medical Research Ethics Committee approved this prospective human study. Written informed consent was obtained from all 12 participating patients (10 female, two male, mean age 73.3 years \pm 8.6 years; age range 62.0-90.0 years) and BMI was calculated. The study was performed between January 2010 and May 2010.

The inclusion was in principle consecutive, but some selection was made to include six patients with a BMI ≤ 30 kg/m² and six patients with a BMI >30 kg/m², for later stratified filter performance analysis according to BMI. Out of 15 eligible patients meeting the inclusion criteria of the study, three patients declined to participate. The inclusion criteria were outpatient status, age above 60 years due to the reduced radiation sensitivity to the additional radiation burden of the study acquisitions compared to younger patients, ability to give written informed consent, referral for a standard contrast-enhanced abdominal CT, absence of known gross pathology in the pancreatic region, and absence of history of known contrast reactions.

Clinical indications for abdominal CT examinations were abdominal pain or metastatic work-up of a known malignancy.

Scanning Technique

All studies were performed according to an established research scanning protocol on a 16-channel multi-detector-row CT scanner (Philips 16-slice Mx8000IDT; Philips Medical Systems, Best, The Netherlands) scanner at Drammen Hospital, Norway.

The participating patients were positioned in the scanner gantry isocenter for their standard of care abdominal portal venous phase CT scan. This was carried out with a scan delay of 60

seconds following administration of 100 ml of intravenous iodinated contrast medium (Iomeron 350; Bracco Imaging, Milan, Italy) injected at a rate of 4 ml/second.

After the acquisition of standard of care CT images, a second (12 mGy / 180 mAs, standard dose) and a third (6 mGy / 90 mAs, reduced dose) research image series were acquired in the pancreatic region over an identical scan length of 10 cm. Scanning in the pancreatic region ensured at least partial inclusion of the liver and pancreas to assess the effect of low radiation dose CT and image post-processing filters on low contrast structures of the abdomen. The scanning location for research series acquisitions was determined from the localizer radiograph (L.B., eight years of experience). No additional contrast medium was administered for acquisition of the two research image series

The order of acquisition of 12 mGy and 6 mGy research image series was randomized to avoid bias from the differential phase of contrast enhancement or washout in the two acquisitions. The two image series were acquired after the standard of care abdominal CT (contrast delay of 60 seconds), at 81-86 seconds (earlier phase of contrast enhancement) and at 94-97 seconds (later phase) following injection of the contrast.

Except for the different mAs values, all remaining scanning parameters were kept constant at 120 kVp, helical acquisition mode at 0.938:1 pitch, 30 mm table feed per second, 0.75-second gantry rotation time and 16 x 1.5 mm detector geometry. For both research image series, 2 mm reconstructed section thickness images were obtained with a 1 mm inter-section interval using a standard soft tissue reconstruction kernel (Standard C, Philips Medical Systems).

Automatic exposure control (AEC) techniques were not used for acquisition of research images as we wanted to assess 2D and 3D adaptive filters at fixed 50% tube current reduction, as described in prior studies with noise reduction filters and adaptive statistical

iterative reconstruction (ASiR, GE Healthcare, Waukesha, WI, USA) (4,9,10). Dose reduction or mA modulation with AEC is not linear at different specified reference levels, and depends on the patient size (or regional attenuation). Consequently, the use of AEC techniques would have provided a differential dose reduction (in smaller or average size patients) or an increment (in large size patients), thus we chose to use the fixed tube current to obtain a predictable dose reduction for our study.

Both research DICOM image series were de-identified and exported offline for post-processing of the reduced dose images with 2D and 3D adaptive non-linear filters (ContextVision Inc., Linköping, Sweden). After post-processing (see Appendix), all four image series (baseline standard and reduced dose image series, reduced dose 2D and 3D filtered image series, (Fig. 1) were imported into our picture archiving and communication system (PACS) (Carestream Health, ver. 5.2.1; Rochester, NY, USA) for image evaluation. In our study we chose a more aggressive 3D noise reduction for patients weighing more than 90 kg than for patients smaller than 90 kg, to match the higher noise level in the larger patients. These settings were selected based on preliminary image evaluation by the two co-authors (L.B. and Ö.S.) who did not take part in the formal image quality assessment of the 2D and 3D filters.

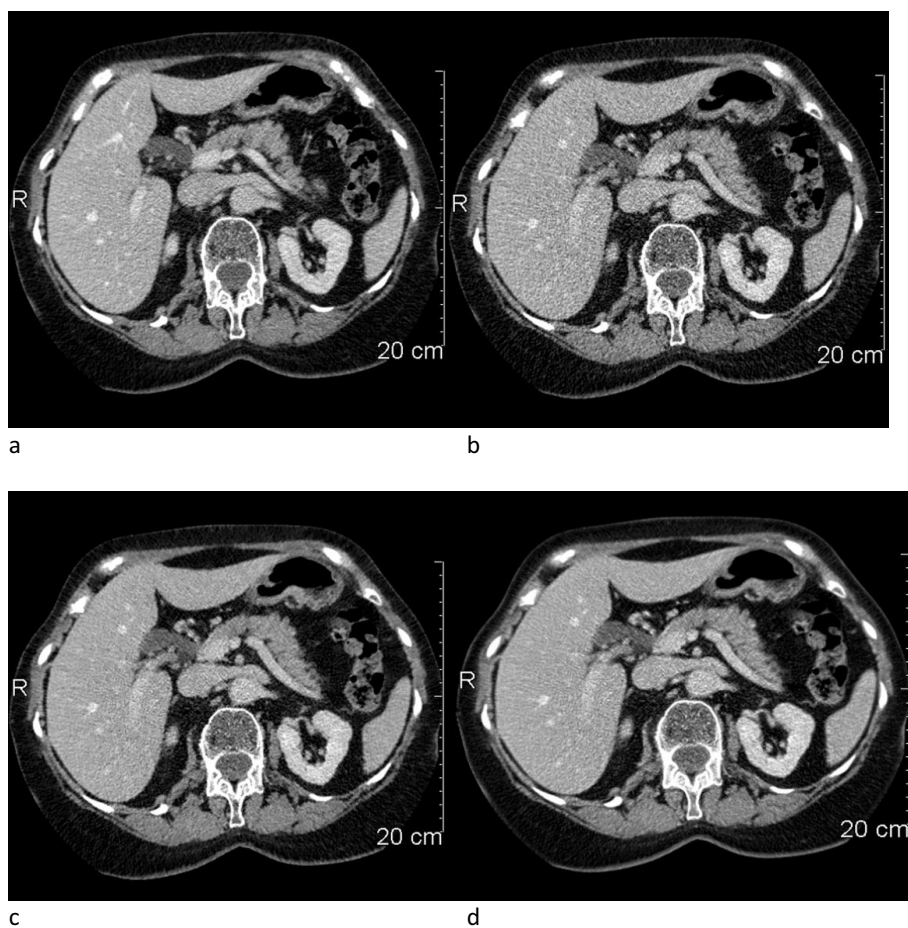


Fig. 1 (a) Axial images of the upper abdomen, 180 mAs and $CTDI_{vol}=12$ mGy. **(b)** Axial images of the upper abdomen, 90 mAs and $CTDI_{vol}=6$ mGy. **(c)** Axial images of the upper abdomen, 2D filtered 90 mAs $CTDI_{vol}=6$ mGy. **(d)** Axial images of the upper abdomen, 3D filtered 90 mAs $CTDI_{vol}=6$ mGy

Subjective image quality

Six experienced radiologists (two abdominal and four general radiologists, average experience of 12 years in reading abdominal CTs) performed a blinded randomized

assessment of the images on a DICOM-calibrated 3 megapixel PACS monitor. Image evaluation was performed with no constraints on interpretation time, window width or level settings or use of image zoom or pan functions. Before formal image evaluation, all radiologists were trained on different aspects of image grading using five pairs of image series.

Each radiologist independently performed a blinded side-by-side comparison of two image series at a time for a total of six comparisons in random order for each of the 12 patients ($n = \text{six comparisons} \times 12 \text{ patients} \times \text{six radiologists} = 432 \text{ total comparisons}$): reduced dose 3D filtered vs. standard dose baseline, reduced dose 3D filtered vs. reduced dose 2D filtered, reduced dose 3D filtered vs. reduced dose baseline, reduced dose 2D filtered vs. standard dose baseline, reduced dose 2D filtered vs. reduced dose baseline, and standard dose baseline vs. reduced dose baseline images.

All radiologists evaluated five criteria, including delineation of pancreatic contours in relation to surrounding intra-abdominal fat, stomach, duodenum and neighboring veins; delineation of intrahepatic portal and hepatic veins; delineation of the common bile duct; subjective image noise; and overall diagnostic acceptability. Overall diagnostic acceptability was defined as the quality of normal anatomy reproduction and suspected ability to visualize pathology. Each criterion was rated on a five point scale (−2: left side images certainly better than right side images, −1: left side images probably better than right side images, 0: image stacks equivalent, +1: right side images probably better than left side images and +2: right side images certainly better than left side images). To enhance blinded randomization for image evaluation, the order of the image series displayed on the right and left sides was also randomized.

Objective Image Quality

CT numbers (Hounsfield value (HU)) and objective noise in terms of standard deviation (SD) of the HU were measured with two uniform circular regions of interest (ROIs) with a diameter of 10-20 mm for the abdominal aortic lumen and 20-30 mm in a homogeneous part of the right hepatic lobe (L.B.).

Height and weight of all patients were measured prior to the CT examinations. We recorded the volume CTDI and Dose length Product (DLP) for both 90 and 180 mAs image series from the dose information page. Estimated effective doses for the two image series were determined using the International Commission for Radiation Protection (ICRP) 103 tissue weighting factors (11) and CT-expo v2.0 (12).

Statistical Analysis

Subjective image quality was analyzed using visual grading regression (ordinal logistic regression), which is suitable for the ordinal scoring system (13). Visual grading regression allows for simultaneous evaluation of effects and interactions of different independent variables, such as imaging equipment, types of post-processing techniques, variations in patient size and contrast enhancement phases as well as differences between patients and between observers. In our statistical model, subjective image quality scores for the reduced dose 3D-filtered images were compared to each of the other image series. Objective image quality parameters were assessed using a mixed linear model with type of image (exposure and filtering) and contrast enhanced phase as two fixed effects, and patient identity as a random effect. Pair-wise comparisons between types of images were made with the Tukey HSD test. Computations were performed with JMP 9.0.0 (SAS, Cary, NC, USA).

Results

The mean BMI of the 12 patients included in our study was 27.7 kg/m² (standard deviation, SD= 5.9; range = 17.8 - 36.6 kg/m²).

Objective Image quality

Objective image quality metrics, mean HU-number and their SD in the liver and abdominal aorta are summarized in Table 1. The image noise expressed as SD of the HU-number in the aorta and the liver was significantly lower in the 3D filtered images than in the unfiltered reduced dose images, but no significant differences were seen between 2D and 3D filtered images or between any filtered reduced dose images and normal dose images. When analyzing normal dose and 50% reduced tube current images according to contrast phase, there was no significant difference in image noise between the early and delayed phase. When the analysis was restricted to the subpopulation defined by BMI above 30 kg/m², the same pattern was found, except that the image noise in the aorta was now significantly higher in 2D filtered than in normal dose images. For patients with BMI below 30 kg/m², however, both the 3D filtered and the 2D filtered reduced dose images had significantly lower noise than the normal dose images in the aorta, and the noise was significantly lower in 3D filtered than in 2D filtered images, whereas no significant difference was found in the liver between 2D filtered, 3D filtered or normal dose images.

As shown in Table 1, there were no significant changes in mean HU values in the aorta and liver parenchyma when comparing unfiltered, 2D filtered and 3D filtered images, while the mean HU in the liver parenchyma decreased significantly from the early to delayed contrast phase.

Table 1 Results of objective measurements analyzed with mixed linear model. Mean HU and mean noise (SD of the HU-number) ± 1 SD. Dose levels and filtering methods are compared to the 3D-filtered reduced dose images; early contrast phase is compared to late contrast phase

Image parameter	Normal dose	Reduced dose unfiltered	Reduced dose 2D-filtered	Reduced dose 3D-filtered	Early contrast phase	Late contrast phase
Mean HU number in aorta	117.1 \pm 16.1*	119.8 \pm 15.4°	119.9 \pm 15.1°	121.0 \pm 15.3	120.6 \pm 17.7°	118.2 \pm 12.2
SD of HU number in aorta	35.0 \pm 12.9°	50.2 \pm 20.4*	39.4 \pm 20.7°	35.8 \pm 17.9	40.3 \pm 21.3°	39.9 \pm 16.1
Mean HU number in liver	96.5 \pm 17.7°	96.9 \pm 17.5°	96.8 \pm 16.9°	97.0 \pm 17.2	97.7 \pm 19.3*	95.9 \pm 14.1
SD of HU number in liver	25.6 \pm 9.8°	39.1 \pm 18.5*	28.5 \pm 17.2°	26.1 \pm 15.6	29.4 \pm 18.2°	30.2 \pm 14.1

*) $p < 0.05$; °) not significant

Radiation doses

The CTDI_{vol} and DLP for the standard and reduced dose image series were 12 mGy, 169 mGy.cm and 6 mGy, 85 mGy.cm, respectively. Corresponding estimated effective doses for these extra image series (average for male and female, standard sized human phantoms) were 3.2 mSv and 1.7 mSv.

Subjective image quality

Subjective image quality data from the pair wise evaluation of all six readers are summarized in Fig. 2a-e. Overall analysis showed significant differences between image noise, overall diagnostic acceptability and delineation of the pancreas, hepatic veins and common bile duct in baseline standard and reduced dose images ($p < 0.001$). All these parameters were also rated as significantly superior in 2D and 3D filtered reduced dose images as compared to the baseline reduced dose images ($p < 0.001$). Compared to the 3D filtered (Table 2) reduced dose

CT images, 2D filtered reduced dose images had higher subjective noise and lower diagnostic acceptability ($p<0.001$) in addition to inferior delineation of the pancreas, hepatic veins and common bile duct ($p<0.001$, $p<0.001$ and $p<0.01$, respectively). Subjective image noise did not differ significantly between baseline standard dose and 3D filtered reduced dose images ($p>0.05$), but there were differences in the delineation of the pancreas, hepatic veins and common bile duct, which were all significantly better in the standard dose images ($p<0.001$, $p<0.001$ and $p<0.01$, respectively).

BMI-stratified analysis (Tables 3 and 4) revealed no significant difference between delineation of the hepatic veins, pancreas and diagnostic acceptability in 3D filtered reduced dose images and standard dose baseline images ($p>0.05$) in patients with BMI below 30 kg/m². In these subjects, subjective image noise and delineation of the common bile duct in 3D filtered reduced dose images were deemed to be superior to the standard dose baseline images ($p<0.05$ and $p<0.001$, respectively). In patients with BMI above 30 kg/m², on the other hand, 3D filtered reduced dose images were deemed inferior to baseline standard dose images for all image quality parameters. Both the reduced dose unfiltered and 2D filtered reduced dose images were deemed inferior to the standard dose baseline images, regardless of patient size.

No significant differences were noted between the early and delayed phase CT image series for any of the subjective image quality metrics ($p>0.05$), except for delineation of the hepatic veins, which was rated as significantly better in early phase images as compared to the delayed phase images ($p<0.01$) (Fig 2b).

Fig. 2 Results from the subjective image quality evaluation for the five image quality criteria.

The columns show the percentage of score alternatives assigned to the image series in question. Score 2 indicates that the image series in question was scored as definitely superior to the alternative, score 1 that it was rated as probably superior to the alternative, score 0 that the alternatives were rated as equivalent, score -1 that the image series was rated as probably inferior to the alternative, and score -2 that it was rated as definitely inferior to the alternative.

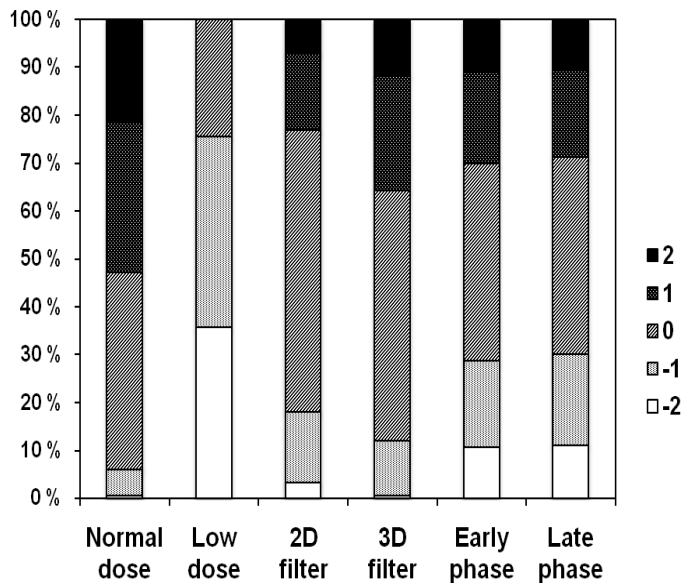


Fig 2a Favorable vs. unfavorable scores for image quality criterion 1: Delineation of pancreas.

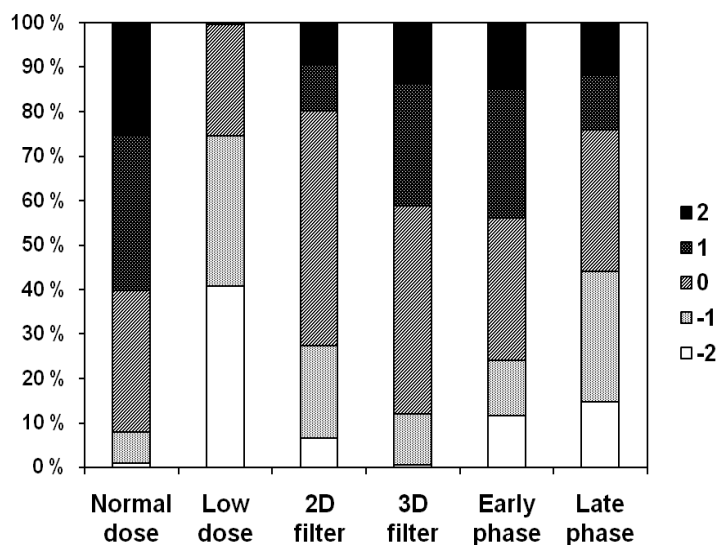


Fig 2b Favorable vs. unfavorable scores for image quality criterion 2: Delineation of veins in liver.

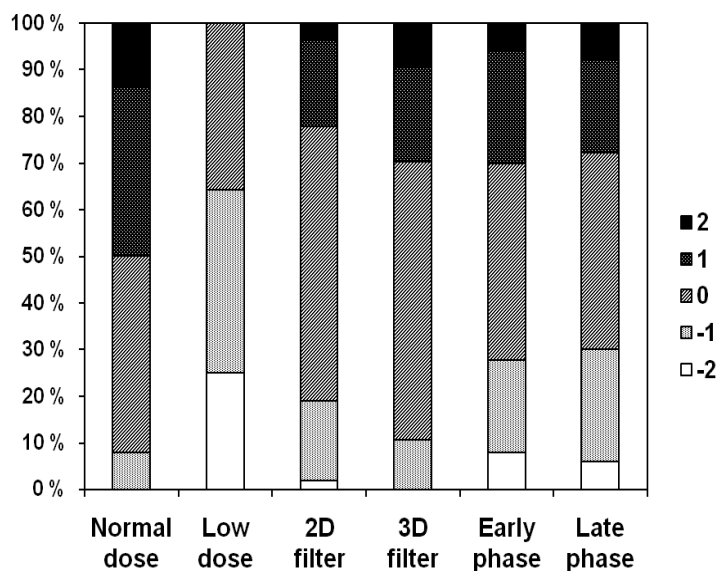


Fig 2c Favorable vs. unfavorable scores for image quality criterion 3: Delineation of the common bile duct.

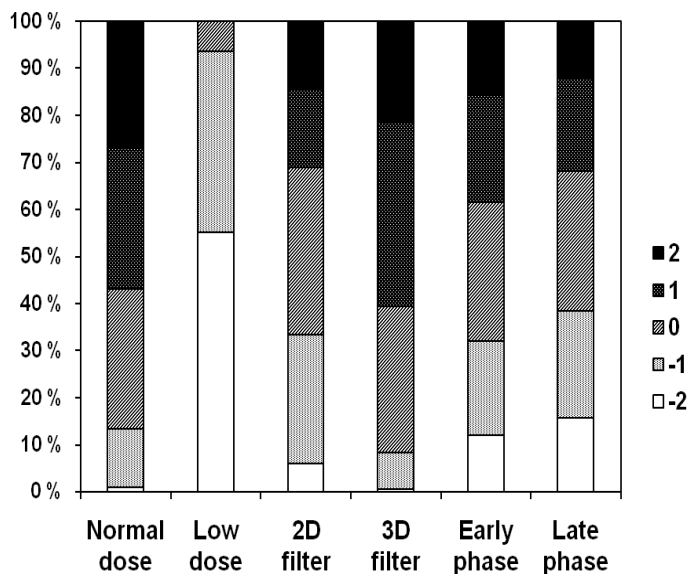


Fig 2d Favorable vs. unfavorable scores for image quality criterion 4: Image noise.

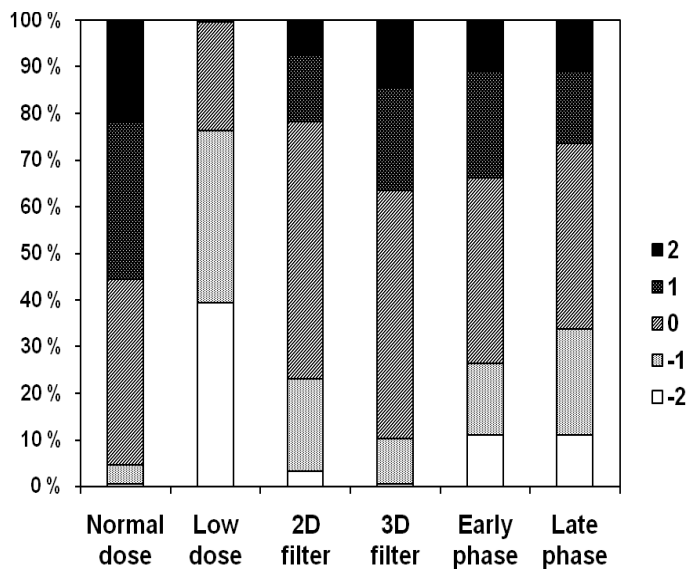


Fig 2e Favorable vs. unfavorable scores for image quality criterion 5: Overall diagnostic acceptability.

Table 2 Results of subjective image quality evaluation of all patients, analyzed by Visual Grading Regression. Positive values denote the increased probability of higher scoring values compared to the 3D-filtered reduced dose images (for the first three columns) or compared to the late contrast phase (for the last column)

Image quality criterion	Normal dose	Reduced dose unfiltered	Reduced dose 2D-filtered	Early contrast phase
1: Delineation of pancreas	0.785***	-3.284***	-0.487**	-0.011°
2: Delineation of veins in liver	0.725***	-3.325***	-0.980***	0.583***
3: Delineation of the common bile duct	0.595**	-2.714***	-0.532**	-0.051°
4: Image noise	-0.136°	-4.905***	-1.244***	0.204°
5: Overall diagnostic acceptability	0.784***	-3.607***	-0.860***	0.193°

*) $p < 0.05$; **) $p < 0.01$; ***) $p < 0.001$; °) not significant

Table 3 Results of subjective image quality evaluation of patients with BMI < 30 kg/m², analyzed by Visual Grading Regression. Positive values denote increased probability of higher scoring values compared to the 3D-filtered reduced dose images (for the first three columns) or compared to the late contrast phase (for the last column)

Image quality criterion	Normal dose	Reduced dose unfiltered	Reduced dose 2D-filtered	Early contrast phase
1: Delineation of pancreas	0.485°	-3.411***	-0.016°	-0.042°
2: Delineation of veins in liver	0.327°	-3.678***	-0.720**	0.832***
3: Delineation of the common bile duct	-0.574*	-3.235***	-0.626*	0.111°
4: Image noise	-1.297***	-7.022***	-1.495***	0.654**
5: Overall diagnostic acceptability	-0.000°	-4.263***	-0.768**	0.486*

*) $p < 0.05$; **) $p < 0.01$; ***) $p < 0.001$; °) not significant

Table 4 Results of subjective image quality evaluation of patients with BMI > 30 kg/m², analyzed by Visual Grading Regression. Positive values denote increased probability of higher scoring values compared to the 3D-filtered reduced dose images (for the first three columns) or compared to the late contrast phase (for the last column)

Image quality criterion	Normal dose	Reduced dose unfiltered	Reduced dose 2D-filtered	Early contrast phase
1: Delineation of pancreas	1.397***	-3.651***	-1.073**	0.122°
2: Delineation of veins in liver	1.392***	-3.595***	-1.544***	0.413°
3: Delineation of the common bile duct	2.438***	-3.352***	-0.788**	-0.098°
4: Image noise	1.038***	-4.602***	-1.545***	-0.047°
5: Overall diagnostic acceptability	1.972***	-3.994***	-1.346***	0.079°

*) $p < 0.05$; **) $p < 0.01$; ***) $p < 0.001$; °) not significant

Discussion

Our study shows that in non-obese patients, 3D adaptive filters can allow radiation doses down to 6 mGy for upper abdominal CT while retaining acceptable image noise and diagnostic acceptability. Compared to baseline 12 mGy images, in obese patients, images acquired with 50% reduction of the tube current are not acceptable with application of either 2D or 3D adaptive filters. Thus, it seems to be more difficult to compensate for a dose reduction in obese patients, where the original image quality tends to be poorer, than in non-obese patients.

With few exceptions (7,14), earlier publications about filter effects on abdominal CT have been based on evaluating images in a randomized but not pair wise manner (5,8;15-17). We

believe that a relative and simultaneous comparison of two image series, rather than an absolute evaluation of one image series at a time, is a more sensitive method to detect subtle image quality differences.

When imaging the pancreas region, thin slices are preferable. In our study, image evaluation was based on a slice thickness of 2 mm with a 1mm interval. Except for a few publications (8,18), most other works on abdominal CT and filter effects have been based on thicker slices (5,7;14-17).

Keeping HU values unchanged through the filtering process is an important issue, since absolute HU values are measured to evaluate, for instance, fluid collection and contrast enhancement. There were no significant changes in mean HU values in the aorta and liver parenchyma after 2D and 3D filtering. The significant decrease in mean HU of the liver parenchyma from the early to late contrast phase was due to contrast washout.

Image noise is inversely related to the square root of the current time product. Even though the study patients varied in BMI, this effect was demonstrated in the mean SD of the HU values of the aorta, where the SD was 50.2 HU for 90 mAs unfiltered images and 35.8 HU for the images acquired with a double dose of 180mAs ($50.2 \times 1/\sqrt{2}=35.5$).

In general, our results are consistent with previously published phantom and patient studies, with non-linear 2D or 3D filters, on noise and radiation dose reduction for abdominal CT (5,7,8,14,16,19,20). For example, Rizzo *et al.* (7) documented successful use of 3D filters to improve image noise while retaining lesion conspicuity and image contrast in abdominal CT examinations, albeit at much higher mAs of 120 or 160 mAs than used in our study. Wessling *et al.* (8) also reported the potential for a 50% dose reduction for liver lesion evaluation with application of their projection space 3D noise reduction filter on abdominal CT.

Normal dose images were deemed significantly superior to 2D filtered images according to subjective image quality. Our findings are consistent with the work of Kalra *et al.*, who documented a loss of image contrast and lesion conspicuity with application of DICOM image-based 2D noise reduction filters to 50% reduced dose abdominal CT (14).

Some recent CT radiation dose reduction studies using hybrid iterative reconstruction techniques have demonstrated up to 50-75% dose reduction for abdominal examinations (9). While these iterative reconstruction techniques promise higher dose reduction compared to noise reduction filters such as the one used in our study, it is important to note that most iterative reconstruction techniques are quite expensive and are only available with the most advanced multi-detector-row CTs. In contrast, noise reduction filters involve lower costs and can be applied to less sophisticated CT scanners with 16 detectors or less, which is the type of CT equipment most commonly used at most facilities. Therefore, we believe that until such time that iterative reconstruction techniques can be applied to older, low-end CT scanners, noise reduction filters can be used to reduce image noise in reduced dose CT images in selected patients.

Our study has some limitations. The study is based on a sample size of only 12 patients. This small number was mainly due to the ethical considerations of exposing patients to additional radiation doses, and is to some extent compensated by using six observers, compared to one to three readers in most earlier studies (4,5,7,14,16,18,21,22). As described above, the chosen sample size was clearly adequate for obtaining significant results for most of the criteria evaluated in our study. Also, when evaluating image quality based on normal anatomy, the inter-patient variation mostly lies in the patient size, which should be covered in our study (BMI ranging from 17.8 – 36.6 kg/m²). However, a larger sample size in terms of more patients would be important for further studies on lesion evaluation.

Objective image noise was evaluated in terms of the SD of the CT-number within a ROI. However, noise properties (such as noise frequency and amplitude) and how they influence the image quality can vary between two differently post-processed image series that have an identical SD of the CT-number within a given ROI. The finding of a significant difference in perceived noise between 3D and 2D filtered images in the qualitative image assessment, but not in the quantitative assessment, could be due to such issues and to image texture differences. Otherwise, qualitative and quantitative noise scoring correlated in our study, indicating that the SD alone can be a valid indicator of noise and thus filter performance.

Another limitation of our study is lack of lesion detection or evaluation. Given the small sample size of our study and the limited 10 cm scan length, we did not expect to find a sufficient number of lesions for evaluation of pathology. The visualization of normal anatomic structures at CT is an established image quality indicator, for instance in the European Union image quality criteria (23), and we believe that our study yields valid preliminary information about the potential clinical value of the post processing filters. In conclusion, the quality of 3D filtered reduced dose abdominal CT images is superior, compared to reduced dose unfiltered and 2D filtered images.

For patients with $\text{BMI} \leq 30 \text{ kg/m}^2$, 3D filtered 50% reduced dose images are comparable to standard dose images.

Declaration of interest:

L.B. received research funding from the Norwegian Radiological Society. I.W.H. and C.F. are employees of ContextVision Inc., Linköping, Sweden. M.K. has received research grants from the Radiological Society of North America and GE Healthcare. The remaining authors, Ö.S., M.S. and F.L. have no pertinent disclosures and had complete access to the study data and the manuscript.

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Appendix

The 3D non-linear adaptive enhancement filter (Contextvision AB, Linköping, Sweden) used in our study is based on the GOP[®] technology of Contextvision, which uses a hierarchical approach to identify image features at different abstraction levels (25). Each pixel is analyzed in relation to its surroundings by local features that are estimated by using a set of filters (Fig. 3). The technique estimates a number of simple, complex and hyper-complex context features. The compiled set of these features forms the contextual information for every location in the image. This information is used to generate a specific filter which adapts to the image signal in every location and individually optimizes each enhanced voxel (volume element). In the CT volumes, the enhancement filter adapts and reduces the amount of noise, giving an increase in the SNR. It preserves the mean HU numbers for each region. With the 3D filter, structures oriented in all directions in space are enhanced according to their natural orientation in the 3D space (x, y and z-axes), compared to the 2D filtering which only works with structures in the 2D plane (in the x and y axes but not in the z-direction). The 3D filter uses the same filter design as the established 2D enhancement. At the time of writing of this manuscript, the 2D filter is a commercially available product (GOPView[®] CT, ContextVision, Inc) but the 3D filter technology still remains a work in progress.

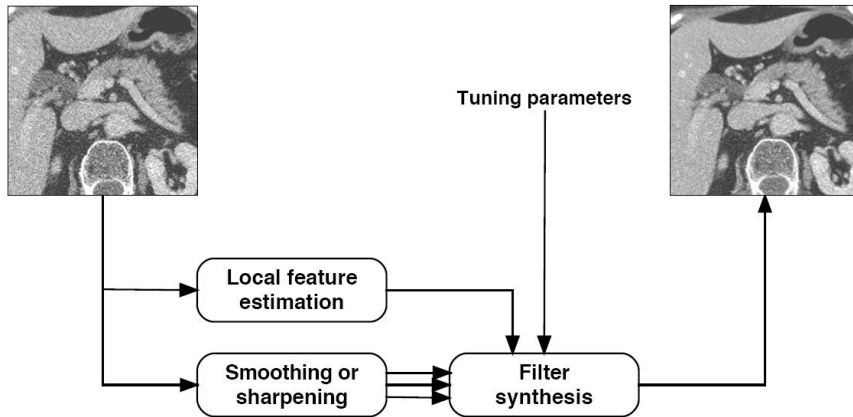


Fig. 3: Principle of adaptive filtering. Each pixel neighborhood is described by computing features such as local orientation, local variance or local phase. Several versions of smoothed or sharpened images are constructed. These versions are combined in each pixel, according to the local features and parameter settings that can be chosen by a competent user in a tuning phase (24).